SELF-EFFICACY, SELF-CARE, AND METABOLIC CONTROL IN PERSONS WITH TYPE 2, DIET AND EXERCISE CONTROLLED DIABETES

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By

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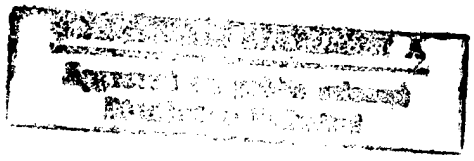

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I HEREBY RECOMMEND THAT THE THESIS PREPARED UNDER MY SUPERVISION BY Lisa M. A. Randall ENTITLED Self-Efficacy, Self-Care, and Metabolic Control in Persons with Type 2, Diet and Exercise Controlled Diabetes BE ACCEPTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF Master of Science.

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ABSTRACT

Randall, Lisa M. A. M.S., Wright State University-Miami Valley College of Nursing and Health, Wright State University, 1998. Self-Efficacy, Self-Care, and Metabolic Control in Persons with Type 2, Diet and Exercise Controlled Diabetes.

Although people with diabetes are often judged by numbers on a computer screen, tight metabolic control remains the ultimate clinical endpoint (Diabetes Control and Complications Trial, 1993). Nurses' understanding of diabetes management coupled with a holistic view of person makes them the optimal professionals to facilitate patient movement toward tight metabolic control.

Diabetes knowledge is essential to self-care, but alone is insufficient to produce and maintain behavioral change. Psychological determinants of self-care and metabolic control must be explored. Self-efficacy (Bandura, 1977) has demonstrated its importance in behavioral modification but has been minimally investigated in diabetes.

This pilot study describes relationships among self-efficacy, self-care, and metabolic control in a convenience sample of six persons with diet and exercise controlled diabetes. Additionally, the study evaluates an integrated multidisciplinary diabetes education program by pre and post measures of these same variables. The study was conducted in 156-bed military hospital in Ohio.

Self-efficacy and self-care were measured by modified versions of Hurley's (1990) self-efficacy and self-care scales; both instruments and their subscales (diet and general) proved reliable (alphas 0.864-0.988). Metabolic control was measured by glycated hemoglobin (%HbA1c).

No statistically significant results were found for either research question. However, correlational relationships were identified between total self-efficacy and total self-care ($r = 0.83$, $p < 0.04$) and between total self-care and metabolic control ($r = 0.28$, $p < 0.58$); total self-efficacy and metabolic control were not related. Also, pre to post measure differences were greatest for total self-care = 7.5 ($p < 0.06$) and metabolic control (HbA1c) = -7.5 ($p < 0.16$) while total self-efficacy changed minimally (4.5, $p < 0.44$).

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ACKNOWLEDGMENTS

To my Mom, Dad, and Husband, Sparky, who listened on end.

To my son, Collin, who spent endless hours in daycare, but always asked lovingly,

"How's your paper, Mommy?"

And

To my very special companion, Specs, who laid at may feet every step of the way.

I love you all dearly. Thank you for standing by my side.

I. INTRODUCTION

Although people with diabetes are often judged by numbers on a computer screen, metabolic measures guide diabetes management. The 1993 Diabetes Control and Complications Trial (DCCT) established the significance of metabolic control. In this study, the maintenance of appropriate or "tight" metabolic control (glycated hemoglobin of 7.2% or less) was directly related to a decreased risk of diabetes-related complications (DCCT, 1993).

With tight metabolic control established as a clinical endpoint, diabetes care providers must understand the means by which to facilitate the patient toward this goal. Diabetes education is the cornerstone of diabetes management, and the nurse's role in this effort is pivotal (Mogensen & Standl, 1993).

However, research attempting to link improved diabetes knowledge to improved metabolic control has produced varied results. Some researchers believe that diabetes education *alone* is insufficient to produce and maintain the behavioral changes necessary for achieving tight metabolic control (Bloise, Maldonato & Assal, 1997; Bradley, 1995; Day 1995; Dunn 1990). In contrast, meta-analytic review and prediction have demonstrated that improved diabetes knowledge does indeed lead to improved metabolic control, but that this relationship is usually mediated through improved diabetes self-care (Brown, 1988 & 1990; Brown & Hedges, 1994). At present, the general assumption remains that diabetes knowledge is a major factor contributing to metabolic control.

Additionally, varied findings have come out of studies that examined the relationship between diabetes knowledge and self-care. However, the assumption

persists that knowledge is a major factor contributing to diabetes self-care (Glasgow, 1991). In contrast, Bradley (1995) warned that nonadherence frequently exists even when one *knows* what he should do.

Although diabetes knowledge appears to contribute to metabolic control, metabolic control is extremely complex in nature. Jacobson, Adler, Wolfdorf, Anderson and Derby (1990) proposed that metabolic control was the result of many complex, intricately interrelated physiological, psychological, sociological and environmental factors. Thus, research has turned to investigating factors other than knowledge that might influence self-care, and metabolic control (Glasgow & McCaul, 1982. Self-efficacy, a cognitive function, has been identified as one of the most influential variables determining what actions one will incorporate into their personal self-care regimen (Kingery & Glasgow, 1989).

Self-efficacy was first examined in diabetes in the early 1980s (Glasgow and McCaul, 1982). Since then, self-efficacy has been repeatedly linked to self-care, and the strength and direction of the relationship is such that self-efficacy is considered predictive of self-care (Crabtree, 1987; Glasgow, Toobert, Riddle, Donnelly, Mitchell, & Calder, 1989; Kingery & Glasgow, 1989; McCaul, et al., 1987). However, research that attempted to describe the relationships of self-efficacy to metabolic control and self-care to metabolic control has provided mixed results (Padgett, 1991). Additionally, minimal information is available on efforts that attempt to enhance diabetes self-efficacy (Hurley & Shea, 1992), and no published reports were found describing self-efficacy in the Type 2, diet and exercise controlled population.

Statement of the Problem

The impetus for tight metabolic control is great in diabetes care. Diabetes knowledge is essential to diabetes self-care but may not improve metabolic

control. Diabetes self-efficacy is known to influence self-care, but further research is needed to clarify the relationships between self-efficacy and metabolic control, and self-care, and metabolic control. Additionally, limited information is available on efforts to enhance diabetes self-efficacy. Also, no published research was found that examined self-efficacy in the Type 2, diet and exercise controlled diabetes population.

Significance and Justification

Approximately one in 17 people in the US have diabetes (Buchanan & Davidson, 1997), and more than 90% of these are of the Type 2 genre (Haire-Joshu, 1996). Predictions indicate that the Type 2 population will continue to grow: by 2015, the diabetes age group between 45 and 65 will have doubled, and the diabetes age group 65 and older will have grown by 1.7% per year (Helms, 1992).

Diabetes directly or indirectly affects everyone in this country. Diabetes is the fourth leading cause of death in the US with more than 385,000 people dying each year (ADA, 1996). The indirect costs of diabetes-related disability, morbidity and mortality has been estimated at $46,626.2 million dollars, while direct costs of inpatient and outpatient care was assessed at $45,222.7 million (ADA, 1996). Thus, total diabetes expenditures in the US exceeded $90 billion in 1992 (ADA, 1996).

Because of its impact, diabetes has been a federal healthcare priority since the late 1970s (Brandsome, 1992). Efforts have primarily focused on reducing diabetes prevalence and controlling diabetes-related complications. Today, this federal initiative is guided by Healthy People 2000 (1991) which seeks to decrease diabetes-related disabilities by 15%, and decrease diabetes-related deaths by 11%.

Although public effort brought attention to diabetes and diabetes care issues, significant efforts to improve diabetes care did not occur until the release of the 1993 Diabetes Control and Complications Trial results (DCCT). In this

landmark longitudinal study (6.5 years) of 1,441 insulin-dependent diabetes patients (Type 1), tight metabolic control (average glycated hemoglobin of 7.2%) was shown to decrease the occurrence and severity of diabetes-related retinopathy, nephropathy, and neuropathy by 50-75% (DCCT, 1993).

In 1995, a randomized control trial similar to the DCCT was conducted in Japanese patients with Type 2 diabetes. Although a much smaller study (n = 110), findings indicated that tight metabolic control (maintained at a near-equivalent level to the DCCT) resulted in a comparable reduction of microvascular complications (OhKubo, Kishikawa, Araki, Miyata, Isami, Motoyosyi, Kojima, Furuyoshi, & Shichiri, 1995). Although further research was suggested, experts stated that similar long-term benefits of intensive diabetes management should be expected in the Type 2 population when comparable DCCT glycemic control is maintained (ADA, 1997a).

With the current emphasis on intensive diabetes management and diabetes education recognized as a cornerstone of diabetes management, the importance of diabetes education has never been greater. Mogensen and Standl (1993) described the nurse as the critical educational resource for the diabetes patient and, at times, the professional who has the greatest impact on psychosocial well-being.

Additionally, the move towards intensive diabetes management has brought forth the concept of the diabetes treatment team. Thus, diabetes education has shifted from a more *traditional* mode of one-on-one instruction to that of *enhanced* (Padgett, Mumford, Hynes & Carter, 1988). Enhanced diabetes education is considered optimal and is that which is provided by an integrated, multidisciplinary team of professionals who specialize in the care of the patients with diabetes (Mogensen & Standl, 1993). Moreover, the evaluation of diabetes education must now demonstrate the impact of the team in totality and is best

accomplished through multiple measure, outcome studies (Abourizk, O'Connor, Crabtree, & Schnatz, 1994).

A review of diabetes outcome research indicates that more studies of this genre are needed and that other factors beside knowledge need investigation. Although diabetes education has existed since the advent of insulin in 1922 (Mogensen & Standl, 1993), empirical evaluation did not occur until 50 years later (Miller & Goldstein, 1972). However, since then, diabetes outcome research has focused excessively (more than 100 published, and possibly twice that many unpublished) on the singular component of knowledge, mostly as related to metabolic control (Glasgow & Osteen, 1992). Additionally, Hamera (1992) noted that nurses performing diabetes outcome research primarily focused on the immediate intervention of education, rather than on the long-term effects that education might have in maintaining disease control and preventing complications. Thus, Hamera suggested that attention shift toward the identification and description of relationships that predict metabolic control. Glasgow and Osteen's review (1992) of diabetes outcomes research specifically suggested further investigation of the psychological variables; self-efficacy was high on the list.

Self-efficacy is a psychological variable that has been identified as an important factor in the decisions one makes of the actions he will take (Bandura, 1977b). The significance of self-efficacy in modifying health behaviors has been demonstrated in many other areas: overcoming depression and anxiety, stress reduction, smoking cessation, alcohol abstinence, weight reduction, exercise, use of contraception, prevention of AIDS, pain management and control, coping with arthritis and chronic obstructive pulmonary disease, and recovery from myocardial infarction (Holman & Lorig, 1992; Kavanaugh, et al., 1993; O'Leary, 1985; Schwarzer, 1992; Strecher, DeVellis, Becker, & Rosenstock, 1986).

Although self-efficacy has received much attention in other areas of research, Kavanaugh, Gooley, and Wilson (1993) noted that little information was available on the role of self-efficacy in diabetes. Also, Russell Glasgow, at the 14th International Diabetes Federation Congress (1991), listed self-efficacy as a concept insufficiently studied in diabetes outcome research (Glasgow & Osteen, 1992).

Review of diabetes self-efficacy literature does not produce any studies of this concept in persons with Type 2, diet and exercise controlled diabetes. Persons with Type 2, diet and exercise controlled diabetes *may* be in an earlier stage of the diabetes disease process. Therefore, this population may have a greater opportunity to curb or avoid devastating long-term complications by incorporating positive self-care behaviors.

However, adherence to diet and exercise diabetes regimens is known to be generally poor and is thought to be the result of multiple contributing factors (Glasgow, 1991). First, diet and exercise regimen behaviors are the most difficult diabetes behaviors to change and maintain (Glasgow, 1991; Rubin, Peyrot, & Saudek, 1989). Secondly, cognitive decisions to adhere or not adhere are burdensome and unending ongoing (Kingery & Glasgow, 1989). Lastly, self-efficacy scores for diet and exercise behaviors have typically been lower than for other regimen behaviors (Glasgow, et al., 1989).

Statement of the Purpose

The purposes of this study are: (1) to describe the relationships among self-efficacy, self-care, and metabolic control, and (2) to examine the difference between pre and post treatment measures of self-efficacy, self-care, and metabolic control. The target population was persons with Type 2, diet and exercise controlled diabetes; the treatment was an outpatient, integrated, multidisciplinary diabetes educational intervention.

Research Questions

1. What are the relationships among self-efficacy, self-care, and metabolic control in persons with Type 2, diet and exercise controlled diabetes?
2. What is the difference between pre and post measures of self-efficacy, self-care, and metabolic control in a group of persons with Type 2, diet and exercise controlled diabetes undergoing an outpatient, integrated, multidisciplinary educational intervention?

Definition of Terms

Type 2, Diet and Exercise Controlled Diabetes

According to the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (1997, p. 1183), "diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both." This same group noted that Type 2 diabetes is typified by an inadequate insulin secretory response and by insulin resistance at the target tissues. Type 2 diabetes is primarily treated with diet, exercise, and anti-diabetes medications, which include oral hypoglycemics and/or insulin.

For this study, patients diagnosed by their healthcare provider as having Type 2 diabetes were targeted. Those who controlled their diabetes by diet and exercise alone were selected by reviewing the patient's pharmacological computer record, and excluding any person who was ordered anti-diabetes medications.

Self-Efficacy

Diabetes self-efficacy is defined as: "the judgment of one's own capability to monitor, plan, and carry out diabetes activities of daily living" (Hurley & Shea, 1992, p. 148). Diabetes self-efficacy is measured using a modified version of Hurley's (1990) *Insulin Management Diabetes Self-Efficacy Scale (IMDSES)* (Appendix

A). The modified version is called the *Nonmedication-Taking Diabetes Self-Efficacy Scale (NMTDSES)* (Appendix B).

Self-Care

Diabetes self-care is defined as: the behaviors or actions performed daily to maintain control of one's particular type of diabetes. Diabetes self-care is measured using a modified version of Hurley's (1990) item-for-item corollary to the IMDSES, the *Insulin Management Diabetes Self-Care Scale (IMDSCS)* (Appendix A). The modified version is called the *Nonmedication-Taking Diabetes Self-Care Scale (NMTDSCS)* (Appendix B).

Metabolic Control

A percent glycated hemoglobin (HbA1c) is used to measure metabolic control, and is defined as: a whole blood laboratory test that provides an accurate long-term index of a patient's average blood glucose level over a period of 100-120 days (Pagana & Pagana, 1995). Optimal or *tight* metabolic control is defined as a HbA1c of less than 7% in accordance with the American Diabetes Association standards (ADA, 1997 b & c).

Summary

Diabetes directly or indirectly effects nearly all Americans. A reduction of diabetes complications is sought, and tight metabolic control is the means to achieve this goal. Because diabetes education is a cornerstone of diabetes management, diabetes educators will be instrumental in assisting diabetes patients towards this clinical endpoint. An improved understanding of factors thought to contribute to metabolic control will better prepare diabetes educators to facilitate this goal: Self-efficacy is one such factor.

Minimal self-efficacy research has been conducted in diabetes, and findings have been varied. First, self-efficacy has been shown to predict self-care, but the

relationships between self-efficacy and metabolic control, and self-care and metabolic control are less clear. Secondly, little information is available on programs that enhance self-efficacy. Lastly, no published self-efficacy information is available for the Type 2, diet and exercise controlled diabetes population---a population that may require the greatest self-efficacy to maintain the most difficult self-care behaviors of diet and exercise. Therefore, the purpose of this study is to describe the relationships among self-efficacy, self-care, and metabolic control, and to examine the pre to post educational differences between these variables.

II. REVIEW OF LITERATURE

The purpose of this literature review is to explore the concepts of self-efficacy, self-care, and metabolic control, to gain understanding of relationships among these variables, and to investigate research on self-efficacy enhancement. An adapted version of C. David Jenkins' (1995) "Pathways for Evaluating Integrated Diabetes Management Programs" will be used as a conceptual model to explain the relationships among self-efficacy, self-care, and metabolic control. The Social Cognitive Theory (Bandura, 1977a) is used by Jenkins (1995) and will serve as the theoretical basis for discussing self-efficacy (Bandura, 1977b).

Self-Efficacy, Self-Care, and Metabolic Control

Self-Efficacy

The term self-efficacy is synonymous with the name Albert Bandura and the theory of Social Learning (Cognitive) (1977a). The Social Cognitive Theory is an interactional theory of causation. This theory supports the human capability for *self-regulation* (the ability to use forethought and judgment) through the mediation of *reciprocal determinism*. Reciprocal determinism describes the complex interaction between *personal factors, environment,* and *behaviors*. *Self-efficacy* makes its contribution to reciprocal determinism through the human process of *self-reflection*, which then contributes to the influence made by *personal factors* (Bandura, 1977b).

The concept of self-efficacy is derived from the inherent human need to have control over events that affect one's life, and is defined as the "belief in one's

capabilities to organize and execute the courses of action required to manage prospective situations" (Bandura, 1995, p.2). Personal control offers the power to influence certain events, allows for some degree of predictability, and fosters adoptive preparedness. People's beliefs in their causative capabilities affect how they think, their level of motivation, their affective state, and their choice of actions (Bandura, 1995).

Perceived self-efficacy (the self-judgment of one's efficacy) is thought to affect behavior in a number of ways: (1) the fulfillment or nonfulfillment of a behavior (the decision to attempt or avoid an action based on the individual's perceived ability to complete the task successfully), (2) the amount of effort dedicated to the behavior, (3) the duration of persistence in that behavior, and (4) the emotional reaction elicited if there is failure in that behavior (coping). Perceived self-efficacy is not a generalized feeling but must be described (high vs. low) in relation to a specific task (Bandura, 1977b).

Feelings of self-efficacy (perceptions) or the degree of self-efficacy towards a given task are thought to develop from four sources: enactive attainment, vicarious experience, verbal persuasion, and physiological state (Bandura, 1977a & b, & 1995). *Enactive attainment*, the most influential of the cognitive informational sources, stems from an individual's past successes and accomplishments (mastery). *Vicarious experience* occurs when an individual identifies with a model and compares himself/herself with this observed experience (modeling). *Verbal persuasion* is the influence produced by an informant and is only as powerful as the recipient of the information allows it to be (confidence in the informant). *Physiological state* has input when the individual perceives somatic signals (symptoms) as significant.

Together, these four contributors produce a feeling of efficacy for some particular task. However, Bandura noted that no matter how capable someone

might feel about performing a behavior, the individual must have the *knowledge* (skills), and the appropriate *incentives* and motivation (*outcome expectations*) to successfully complete the task (Bandura, 1986). Efficacy self-appraisal is also affected by the *degree and amount of attention* the individual devotes to the task, the *weight of importance* the individual assigns the task, and the *degree to which the outcome is attributed* to the individual or to aspects beyond the individual's control.

Self-efficacy must be measured in a task-specific manner and is done so on one of three parameters (Bandura & Adams, 1977). The level of self-efficacy (*magnitude*) is usually measured by a graded series of steps that range from simplistic to complex; persons then select the steps that they feel capable of attaining. *Strength* of self-efficacy is ideally measured in two steps. First, persons select behaviors that they feel capable of performing; then, they rate the degree of certainty they feel toward completing each of those tasks. *Generality* concerns the extent to which efficacy expectations about a particular situation or experience generalize to other situations. Most health-related self-efficacy investigations review strength, which has shown to be the most relevant indicator (Schwarzer, 1992).

Support for self-efficacy's role in behavioral change has been attained from both health-related and nonhealth–related fields. Self-efficacy's influence was first demonstrated in experimentation with phobics (Bandura, 1986; Bandura, Adams, & Beyer, 1977). In this research, Bandura enhanced subjects' self-efficacy through the four contributors of mastery, vicarious experience, verbal persuasion and physiological reactions alleviating their subjective fears of relatively safe environments. Since this time, convergent data for the self-efficacy theory has been obtained from a wide variety of primary, secondary and tertiary health promotion and prevention fields: overcoming depression and anxiety, stress

reduction, smoking cessation, alcohol abstinence, weight reduction, exercise, use of contraception, prevention of AIDS, pain management and control, coping with arthritis and chronic obstructive pulmonary disease, and recovery from myocardial infarction (Holman & Lorig, 1992; Kavanaugh, et al., 1993; O'Leary, 1985; Schwarzer, 1992; Strecher, et al., 1986). Currently, Schwarzer (1992) and others believe that self-efficacy's significance is so great that they have promulgated: ....the total effect of self-efficacy on health behaviors exceeds the effects of any single variable. (p. 223). Additionally, self-efficacy's significance has been justified in general motivation, achievement behavior, career choice and development, and athletic attainments (O'Leary, 1985).

O' Leary (1985) was one of the first to assert the concept of self-efficacy in health behaviors, particularly as related to adherence. O'Leary discussed self-efficacy's application in chronic illness where medical regimen nonadherence is near 50%. She quoted studies where self-efficacy was shown to be a better predictor of adherence than that of instilled fear or personal locus of control. O'Leary believed that patients who were fully convinced of the treatment and their abilities to carry out the regimen were more apt to practice their prescriptions faithfully.

Strecher et al. (1986) described self-efficacy's ability to predict and explain health behaviors, and highlighted the importance of these findings for health education. From their review of health-related self-efficacy research, Strecher et al. promulgated self-efficacy's ability to predict short and long-term success in behavior change. Additionally, they noted that *perceived efficacy* had a greater influence on health-related behavioral change than did *true abilities*. Strecher's group stressed the implications of these findings in health education by stating that with knowledge of self-efficacy's predictive nature, health educators should be more readily able to influence behaviors, and thereby diminish noncompliance,

lessen relapse events, and/or enhance regimen adherence. Implementing this knowledge would best be accomplished by first identifying areas where task-specific self-efficacy was low and then initiating a task-specific self-efficacy enhancement program using step-wise progression (building mastery) (Strecher et al., 1986). Strecher et al. discouraged traditional counseling or medical-based methodology in these efforts since they seemed to steal away internal locus of control and reduce self-efficacy.

A more recent application of self-efficacy in chronic disease management focused on improved outcomes (Holman & Lorig, 1992). Holman and Lorig's discussion stressed the significance of self-efficacy in chronic illness self-care and coping. These authors proposed that adequate or enhanced self-efficacy in self-care practices produced positive or improved outcomes. Holman and Lorig supported this assumption with findings from a randomized, prospective study of arthritic patients that underwent a comprehensive self-management program. In this study, little correlation was found between health outcomes, increased knowledge, and self-management practices. Further investigation showed that those who felt that they could achieve some control over the disease and improve their quality of life benefited most from the program. In a four year follow-up study, this group showed a continued rise in self-efficacy (29%), a reported reduction in pain (20%), and a decreased number of physician visits (40%) which translated to a $190-650 savings per patient. Conclusions indicated that self-management education, operating through a vehicle of self-efficacy to enhance coping, significantly reduced pain, depression, and dependence on medical care, while improving participants' physical and social activities.

Diabetes outcome investigations of self-efficacy and other the psychosocial variables is a fairly recent undertaking. The role of behavioral mechanisms in diabetes was first defended in 1982 by Glasgow and McCaul in an editorial that

advocated Bandura's Social Cognitive Theory as the theoretical framework necessary to guide this research. However, research of the psychosocial variables, to include self-efficacy, has been minimal as evidenced by meta-analytical review. For example, neither the 1988 nor the 1990 diabetes education meta-analyses by Brown mentioned the term self-efficacy, and only Brown's 1990 meta-analysis listed a category of psychological outcomes which enveloped just 14 of the 82 studies reviewed. Additionally, Padgett's (1988) meta-analysis, which examined psychological outcomes more definitively, listed a category of "social learning/behavior modification" but failed to recognize self-efficacy.

Currently, discussions of self-efficacy are more prevalent in diabetes literature, however, evidence is needed to further validate this concept and emphasize its importance in diabetes management. Jenkins (1995) believed that patients must feel capable of making a difference in their own health (self-efficacy) to be effective in managing their own regimes (performing self-care behaviors or skills). Although Jenkins did not expand upon the relationship between self-efficacy and self-care, he stated that the absolute pinnacle of behavioral research would be the completion of a longitudinal study (as a follow-up to the DCCT) that quantified the relationship between psychosocial variables, self-care behaviors, metabolic control, and diabetic complications.

Self-Care

Multiple terms (compliance, adherence, self-regulation and self-management) have been used to describe the broad class of patient behaviors required to control one's diabetes. The term self-care predominated the literature and includes behaviors that range from those that are mechanical in nature (medication-taking, self blood glucose monitoring) to those that involve lifestyle changes (diet, exercise) (Glasgow & Osteen, 1992).

Diabetes self-care has been extensively examined for over 30 years. Early diabetes self-care research focused on adherence (compliance) issues as correlated with metabolic control. More recent studies have attempted to identify predictors of self-care and interventions that enhance these predictors. However, despite nearly exhaustive research, diabetes self-care adherence has remained low and research methodology problematic (Glasgow, 1991).

Adherence problems in diabetes self-care are not unexpected (Wing, Epstein, Nowalk & Lamparski, 1986). The impact of a diabetes diagnosis has been described as the sudden expectation that one must assume external control of a once involuntary internal bodily function (Wing et al., 1986). Additionally, this group related the repetitive, unending cognitive processes of diabetes self-care using Kanfer's 1975 theory of self-regulation: with each self-monitored blood glucose test the person must *self-observe* the value, *self-evaluate* the meaning of the value, and *self-reinforce* with the appropriate required response. Wing et al. also discussed the indirect relationship between regimen complexity and adherence, and ranked the complexity of the diabetes self-care regimen at the top.

While the occurrence of nonadherence in diabetes self-care is not debated, attempts to quantify the magnitude of diabetes nonadherence have been controversial. However, despite inconsistencies in methodology, classical studies continue to be reported (Glasgow, 1991). Kurtz's (1990) summary of adherence research indicated that diet nonadherence ranged from 35-75%, insulin nonadherence in administration and technique was as high as 80%, unacceptable foot care was performed in 23-54% of the cases, and nonadherence in urine testing was noted at 43%. One study gave a 93% nonadherence rate for insulin administration, foot care, diet, and urine testing regimens.

Methodological problems in diabetes self-care research have been generally been associated with inconsistent use of terminology, reliance on self-report measures, and lack of standardized measures (Glasgow 1991; Glasgow & Osteen, 1992; Glasgow, Wilson and McCaul, 1985; Goodall & Halford, 1991). Furthermore, diabetes self-care research has generally failed to describe nonparticipants and/or influences that affect study mortality (attrition) (Glasgow, Eakin & Toobert, 1996).

A primary source of confusion in diabetes self-care research has been the use of varied terminology describing the role of the patient in diabetes management. Terms such as self-care, compliance, adherence, self-regulation, and self-management have been interchanged but have major operational differences (Glasgow & Osteen, 1992). In general, adherence is preferred over compliance, and self-care over self-management or regulation.

Second, the reliance on single measures of self-care, particularly self-report, has limited the description of self-care (Glasgow 1991; Glasgow & Osteen, 1992; Glasgow, et al., 1985). Self-report is a limitation in any research because data is heavily influenced by social expectations (Burns & Grove, 1993). Kurtz (1990) offered examples of self-report limitations in diabetes research as related to self-monitored blood glucose testing. In one study, insulin-treated adults were given a monitoring device and not informed of the memory function. Comparisons showed that 30% of the self-reported data was fabricated while 74% was over reported. In a similar study of adolescents and their parents, 40% of the results were fabricated. Another study disclosed that clinicians who had labeled patients compliant according to their home glucose monitoring logbooks had misjudged in 45% of the cases.

Lastly, multiple factors have contributed to the lack of standardized instruments for diabetes self-care measure. First, global measures of adherence (used in earlier studies) have proven inaccurate because regimen compliance in

one self-care aspect can differ significantly from another (Glasgow, McCaul & Schafer, 1987). Second, measures of specific self-care behaviors must reflect current trends in diabetes care, and although the rate of medical advancement has contributed to this problem so have the effects of personal preferences in treatment modalities (Glasgow, 1991). Lastly, self-care measures that have demonstrated reliability have not been reapplied to enhance validity (Glasgow & Osteen, 1992).

Besides instrumentation problems, conceptual issues have further complicated the study of diabetes self-care (Glasgow, 1991). First, self-care has typically not been seen as a multifaceted construct, one where each behavioral dimension is able to elicit a varying degree of adherence that may or may not be statistically related (Glasgow, et al., 1987). Secondly, adherence has not been viewed as relative but is so, because data comes from what the patients *thought* they were told. Self-care's relativity is further complicated by generalized verbal prescriptions such as "exercise more, and eat less". Lastly, diabetes has been seldom regarded as a heterogeneous collection of disorders that extends over the lifespan; e.g., insulin-dependent self-care in a 13 year-old adolescent varies greatly from that in a 67-year-old adult.

However, despite methodological difficulties, research in diabetes self-care persists for two reasons: (1) the fact that more than 95% of diabetes management is done by the patient (Haire-Joshu, 1996), and (2) the fact that self-care is considered a contributor to metabolic control (although weakly associated when found) (Glasgow, 1991; Kurtz, 1990; Goodall & Halford, 1991). Thus, researchers such as Wing et al. (1986) and Lorig and Holman (1992) have strongly advocated the role of diabetes education in self-care by stating that knowledge and skill are sine qua non to the success of the process. The impetus for self-care has been made even stronger by a meta-analysis that demonstrated adherence

was positively linked to metabolic control through knowledge (Brown & Hedges, 1994).

Metabolic Control

Nearly 30 years ago, blood from diabetic patients was found to contain increased amounts of posttranslationally glycated hemoglobin (hemoglobin A1c) (Goldstein, Little, Lorenz, Malone, Nathan & Peterson, 1995). Postranslational glycation involves the attachment of glucose to the amino acid group of the N-terminal valine in the globin beta chain on the hemoglobin molecule (Kolaczynski & Goldstein, 1997). Because this postranslational binding is irreversible, the HbA1c is a direct reflection of the ambient glucose concentration during the life of a red blood cell (100-120 days) (Kolaczynski & Goldstein, 1997). Thus, the percent glycated hemoglobin at any one time reflects the average blood sugar during the previous 100-120 days (Pagana & Pagana, 1995).

Hemoglobin glycation is a normal process in all human beings (Ravel, 1995). In most individuals, hemoglobin is comprised of hemoglobin A (97-98%), hemoglobin A2 (2.5%), and hemoglobin F (0.5%). At any one time, approximately 6-7% of the hemoglobin A (HbA) molecules are modified by the attachment of a glucose molecule. When HbA undergoes glycation, the term glycated hemoglobin or Hemoglobin A1 (HbA1) is applied. The formation of HbA1 occurs very slowly and over the entire 120-day lifespan of the red blood cell (RBC). HbA1 has three components, HbA1a, HbA1b, and HbA1c. HbA1c is the most abundant of the three components comprising 60-70% of HbA1.

Although an elevated HbA1c is generally found in persistent hyperglycemia, the HbA1c is not currently recommended as a diagnostic tool (ADA, 1997b). Significant relationships have been demonstrated between the HbA1c and fasting plasma glucose, glucose peak during the glucose tolerance test, area under the curve of the glucose tolerance test, and mean glucose levels over preceding weeks

(Goldstein et al., 1995). Goldstein, Little and Parker (1984) noted studies where a 1% change in glycated hemoglobin was indicative of a 25-35 mg/dl increase in the mean plasma glucose. Thus, the higher the average daily blood sugar, the higher the percent glycated hemoglobin (Haire-Joshu, 1996).

The HbA1c has been validated as an accurate long-term index of the average blood glucose level, a useful tool for evaluating glycemic control, and an adjunct to clinical decision-making in diabetes management since the mid 1980s (Cohen, 1986; Goldstein et al., 1995). In 1997, the American Diabetes Association recommended that the HbA1c be measured 1-2 times per year in patients with a history of stable glycemic control and quarterly in patients whose therapy has changed or who are in poor glycemic control.

Although considered a standard of diabetes care (ADA, 1997b), the HbA1c is not without problems. Clinical and research concerns have centered on nomenclature inconsistencies, testing frequency and timing disagreements, and assay and/or host-specific limitations.

Nomenclature used to describe the addition of glucose to hemoglobin has changed over time, and lack of standardization has created confusion in the literature (Goldstein & Little, 1994; Kolaczynski & Goldstein, 1997). According to these authors, "glycosylated," "glycosylation," and "glycohemoglobin" were used in earlier studies but are now reserved for *enzymatic* glucose reactions only. The terms "glycated" and "glycation" are used now to describe the *nonenzymatic* attachment of glucose to *proteins* (including hemoglobin). *Total glycated hemoglobin (GHb)* is used to describe the glycation process not only at the valine of hemoglobin but at *all* valines and lysines (Kolaczynski and Goldstein, 1997). Lastly, *Glycated hemoglobin* is technically reserved for describing HbA1; however, because HbA1c comprises 70% of HbA and is the most studied and discussed, the

term *glycated hemoglobin* is frequently used to describe the HbA1c component (Ravel, 1995).

Slight disagreement exists about when the HbA1c first demonstrates change post intervention with even less disagreement about when the HbA1c reflects the total treatment. Kolaczynski and Goldstein (1997) stated that a change in steady state was detectable at 3-4 weeks but that the *new* steady state could not accurately be described until four months post intervention (the lifespan of the RBC).

Assay specific limitations are usually related to chromatographic methods and may be associated with an inability to maintain a uniform analysis temperature, an altered buffer solution pH and/or ionic strength, and/or an inconsistent or inappropriate column size (Kaplan & Pesce, 1996). Additionally, limitations associated with blood collection, storage, and shipping can confound the assay process (Davidson, 1991).

Host-specifics limitations may interfere with the true reflection of the patient's HbA1c. Host-specific limitations known to *increase* glycated hemoglobin levels include: (1) HbF (especially thalassemia), HbC, other negatively charged hemoglobins, (2) uremia, (3) alcoholism, (4) lead poisoning, (5) elevated triglycerides, (6) iron-deficiency anemia, (7) post-splenectomy, (8) hyperbilirubinemia, (9) opiate addiction, and (10) chronic aspirin therapy (Kolaczynski & Goldstein, 1997). Host-specific limitations known to *decrease* glycated hemoglobin levels include: (1) HbS, HbC, other positively charged variants, (2) hemolytic anemias, (3) acute or chronic blood loss, and (4) pregnancy (Kolaczynski & Goldstein, 1997).

The creation of a plethora of glycated hemoglobin assays has been both an advantage and disadvantage. The surplus of assays has allowed clinicians and researchers to selectively eliminate many of the factors known to interfere with

glycated hemoglobin measurement. However, clinical and empirical confusion has festered since no one assay has been identified as the best method or selected as a national/international standard (Goldstein & Little, 1994). Moreover, multiple methods of HbA1c analysis have lead to a diversity of normal values and have inhibited value comparisons among laboratories. Thus, experts have recommended that HbA1c values be compared only if identically processed in the same laboratory setting (Haire-Joshu, 1996; Kaplan & Pesce, 1996).

Because of the number of systems on the market to assess glycated hemoglobin, Goldstein and Little (1994) stressed that clinicians and researchers must knowledgeably evaluate the assays available. Considerations for evaluation should include the type of assay, the nondiabetic reference range, whether the assay is susceptible to unstable intermediates or hemoglobin variants, other known host-specific or method-specific interferences particular to that assay, and reliability and validity testing results. Goldstein et al. (1995) spoke of the National Institute of Health's standard for a with-in-laboratory between-run coefficient: 5% or less. Additionally, the lab should be accredited by the College of American Pathologist (CAP) and should have successfully completed their Survey of Glycated Hemoglobins (Goldstein et al., 1995).

Two major categories of analysis exists: (1) those based on *charge differences* between glycated hemoglobin and non-glycated hemoglobin which include cation-exchange chromatography, electrophoresis, isoelectric focusing and (2) those based on *structural differences* which include affinity chromatography and immunoassay. One of the structural methods, boronate affinity chromatography, has been recognized as a very specific measure of glycated hemoglobin (Baynes, Bunn, Goldstein, Harris, Martin, Peterson & Winterhalter, 1984). Boronate affinity chromatography has been known to limit many of the factors that interfere with glycated hemoglobin analysis (Garlick, Mazer, Higgins, &

Bunn, 1983), and has been associated with a less than 3% variation in replication tests (Kolaczynski & Goldstein, 1997).

Boronate affinity chromatography is a process using phenylboronate resin to separate glycated hemoglobin from non-glycated hemoglobin by detecting ketoamine linkages. Ketoamine linkages are found not only in the HbA1c (beta chain), but also in the lesser glycated hemoglobins (alpha chain) and in certain epsilon amino groups of lysine residues on both the alpha and beta chains. Therefore, the identification of these ketoamine linkages by boronate affinity chromatography yields a more precise, all-inclusive picture of glycation (Garlick, et al, 1983), and is referred to as *total glycated hemoglobin (GHb)* (Goldstein et al., 1995). Because the amount of HbA1c is directly proportional to the GHb, conversion accurately represents the percent HbA1c (Davidson, 1991).

Advantages of the boronate affinity methodology include its ability to exclude many of the known impediments associated with glycated hemoglobin analysis (Davidson, 1991). Boronate affinity chromatography is not influenced by conditions of blood collection, shipping, and/or storage. The specificity of the phenylboronate resin eliminates the influence of unstable or labile hemoglobins (pre-HbA1c and those with aldimine linkages) and the influences of those problems known to cause *falsely elevated values* in other analysis methods. Besides HbF, the boronate affinity assay also excludes interference from the variants of HbC and HbS that are known to *falsely decrease measured levels*.

Disadvantages of the boronate affinity methodology are minimal. This method remains sensitive to analysis temperature variation, and studies have shown that a small portion of glycated hemoglobin is not captured (Kolaczynski & Goldstein, 1997). The greatest limitation associated with boronate affinity chromatography (and all other assays) is the inability to correct for a shortened RBC lifespan found in the aforementioned hemoglobinopathies. Therefore, from

Kolaczynski and Goldstein's (1997) list of conditions affecting glycated hemoglobin levels, only hemolytic anemias, acute or chronic blood loss, and pregnancy remain as interfering factors in boronate affinity chromatography.

Goldstein et al. (1995) noted that in hemolytic anemias, acute blood loss, or any situation where erythrocyte turnover is increased or the erythrocyte pool is enriched with younger cells, that glycated hemoglobin analysis will report falsely low values. Only one study found attempted to quantify the affects of acute blood loss on glycated hemoglobin measures. Starkman, Wacks, Soeldner, and Kim (1983) bled 12 non-diabetic adults of approximately one unit of whole blood (450 ml) and saw significant decreases in all glycated hemoglobin measures, with the mean percent decrease in the HbA1c at 8.6% by high-performance liquid chromatography. The nadir for the HbA1c occurred at four weeks post phlebotomy. No significant correlation was found between the percent estimated blood loss and the percent decrease in either HbA1 or HbA1c.

Panzer, Kronik, Lechner, Bettelheim, Neumann and Dudzak (1982) examined 20 non-diabetic patients who were diagnosed with one of three different types hemolytic anemia and compared those to a group with other forms of hematologic disease and a group considered healthy. Results showed a 3.9% $\pm$ 1% ($p < .0005$) decrease in GHb in the hemolytic group as opposed to the two non-hemolytic groups, and a significant curvilinear correlation (r squared = 0.88, $p < .001$) was identified between glycated hemoglobin levels and red cell survival. Additionally, in two patients who underwent splenectomy, normal hematologic status was attained one week post-surgery; however, GHb did not return to its pre-surgical level until four weeks post-op. This indicates that a 30-day window should elapse before making clinical judgments based on the glycated hemoglobin measure in similar populations.

The presence of a hemolytic anemia has generally been recognized as a factor known to falsely decrease the HbA1c measure. No study or reference specifically listed which hemolytic anemias effect HbA1c measure. Thus, a general definition of anemia was identified and a list of hemolytic anemias obtained to set parameters for exclusion criteria.

In general, anemia is defined as: a reduction in the number of circulating red blood cells per cubic millimeter, the amount of hemoglobin per 100 milliliters (mls), or the volume of packed red cells per 100 mls of blood (Thomas, 1997, p. 96). However, Thomas noted that no specific values denoted anemia and that application of the term was dependent on the person's baseline blood values. Weatherall (1996, p. 3527) provided a specific list of hemolytic anemias that will also be used for exclusion criteria:

- Genetic Disorders of the Red Cell
  - Membrane
    - Hereditary spherocytosis
    - Hereditary ovalocytosis
    - Stomatocytosis
    - Pyropoikilocytosis
    - Other "leaky" membrane disorders
    - March haemoglobinuria
    - Acanthocytosis
  - Haemoglobin
    - Sickling disorders
    - Haemoglobins C, D, and E
    - Unstable haemoglobins
    - Thalassaemia syndromes

- Energy Pathways
  - Hexose-monophosphate shunt
  - Embden-Meyerhof pathway
  - Others
- Acquired Disorders of the Red Cell
  - Immune
    - Isoimmune; Rh or ABO incompatibility
    - Autoimmune; warm of cold antibodies
  - Non-immune
    - Trauma
      - Microangiopathy
      - Valve prosthesis
      - Body surface
    - Membrane defects; PNH [paroxysmal nocturnal haemoglobinuria], liver disease
    - Parasitic disorders
    - Bacterial infection
    - Physical agents, drugs, and chemicals
    - Hypersplenism
    - Defective red cell maturation

Despite these limitations the HbA1c has proven to be an invaluable tool for clinical and research use (Haire-Joshu, 1996). Clinically the percent HbA1c can be used to: (1) evaluate the success of diabetes treatment, (2) compare and contrast the success of past and new forms of diabetic therapy, (3) determine the duration of hyperglycemia in the newly diagnosed diabetic patient, (4) provide a sensitive estimate of glucose imbalance in the patient with mild diabetes, (5) individualize diabetic control regimens, and (6) provide a sense of achievement or create a

realistic view of one's glycemic control (Pagana & Pagana, 1995). For research, the HbA1c has proven to be an indispensable parameter to relate glycemic control and long-term complications as best evidenced by the DCCT (1993) (Haire-Joshu, 1996).

Although the importance of euglycemia was clearly demonstrated by the DCCT (1993), achieving tight metabolic control is no easy matter. Day (1995) pointed out that even within the stringent controls of the DCCT just over eight percent of the intensified treatment group attained a normal HbA1c. Additionally, Day noted that only about 25% of closely monitored diabetic patients even come close to attaining an *acceptable* (near-euglycemic) HbA1c. In contrast, Day pointed out that although many subjects seem unable to attain such goals, perfect control had been documented where motivation was notably high (pregnancy).

Conceptual Framework

Self-efficacy, self-care, and metabolic control are each very different entities, yet together, play a significant role in diabetes management. Diabetes management is a multifaceted concept and process of thoughts, actions and outcomes (Jenkins, 1995). Self-efficacy, self-care, and metabolic control are a few of the important components within the concept of diabetes management and care (Jenkins, 1995).

In an attempt to demonstrate the role of behavioral medicine within the medical model of diabetes management, C. David Jenkins (1995) developed an archetype for evaluating diabetes management. Jenkins' model includes the concepts of self-efficacy, self-care, and metabolic control as well as others, and illustrates the proposed relationships among these variables (Figure 1). Permission has been granted to use and adapt Jenkins' "Pathways for Evaluating Integrated Diabetes Management Programs" (1995, p. 61) as a guide for this research effort (Appendix F).

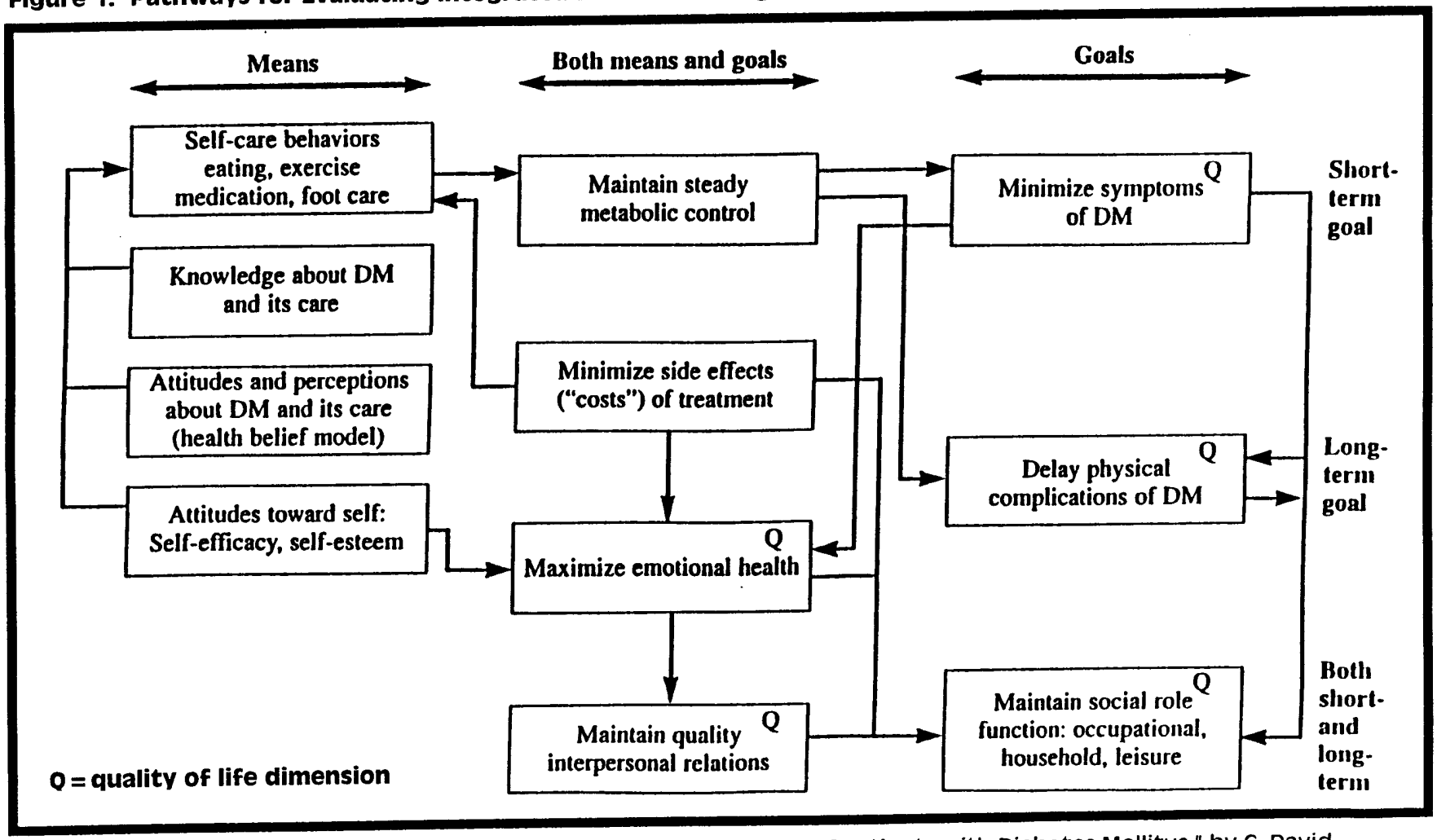
The Model

Jenkins' model (1995) is comprised of three general columns divided into "means," "both means and goals," and "goals" (Figure 1). The *means and goals* and *goals* columns contain concepts generally associated with the medical model of diabetes care. The right-hand *goals* column encompasses ideals of symptom minimization (short-term), delayed physical complications (long-term), and the maintenance of social role functions such as occupational, household, and leisure (both short and long-term). The center *means and goals* column contains the ideals of steady metabolic control, minimization of the side effects associated with treatment (costs), maximization of emotional health status, and the maintenance of quality interpersonal relationships.

The left-hand column, *means*, discusses behavioral components and knowledge. Jenkins (1995) discussed contributing psychological factors using Becker's Health Belief Model and Bandura's Social Cognitive Theory. The Health Belief Model, which has been repeatedly associated with compliance in chronic disease management, is used to explain *attitudes and perceptions about diabetes*. The Social Cognitive Theory, which is generally related to determinants of behavior, is used to explain *attitudes toward self (self-efficacy, self-esteem)*. Lastly, Jenkins adds *knowledge about diabetes* as an essential contributing factor to self-care.

The flow of the diagram proceeds left to right. First, Jenkins lists the components of *knowledge of diabetes, attitudes and perceptions towards diabetes,* and *attitudes towards self (self-efficacy, self-esteem)*. These three components are then shown to affect *self-care behaviors (eating, exercising, foot care)* which is located in this same column. Next, *Self-care behaviors* is arrowed toward *maintaining steady metabolic control* under the center column of *means and goals*. Lastly, *maintaining steady metabolic control* is

Figure 1. Pathways for Evaluating Integrated Diabetes Management Programs.



From "An Integrated Behavioral Medicine Approach to Improving Care of Patients with Diabetes Mellitus," by C. David Jenkins, 1995, *Behavioral Medicine, 21,* p. 61. Copyright 1995 by Behavioral Medicine. Reprinted with permission of the publisher.

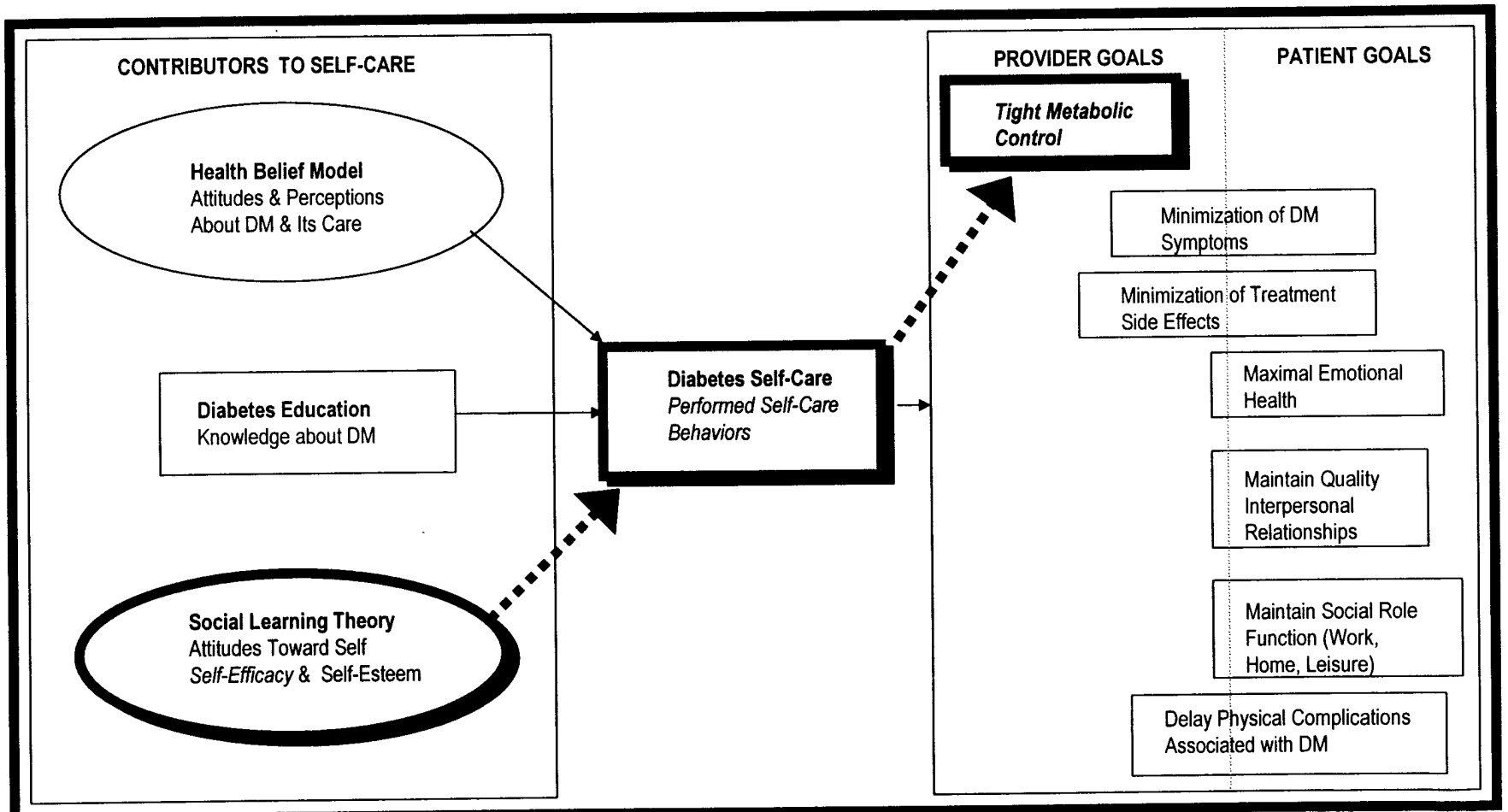
shown to influence *minimization of diabetes symptoms* and *delay of physical complications,* both of which fall under the third and last column entitled *goals.*

In keeping with Jenkins' (1995) ideals for managing and evaluating integrated diabetes care, this researcher has adapted Jenkins' model to highlight the variables under study and more dramatically demonstrate the proposed relationships among these variables (Figure 2). All components of Jenkins' model have been maintained to illustrate the totality of diabetes management. The variables under study have been highlighted to explain that this research only examines a fragment of the diabetes management concept. Most notable are changes made to the model's layout, done to reflect current literature on the proposed temporal ordering of these variables and the researcher's hypotheses about the relationships among these variables.

Three major changes were implemented in Jenkins' (1995) model. First, the center *means and goals* column and the right-hand *goals* column were merged to create a provider-patient goals box. The concepts within this box were arranged in a provider-patent continuum based on an assumed level of importance that each has to these respective parties. Additionally, *maintain steady metabolic* was replaced by *tight metabolic control* to bring attention to this most important treatment goal.

Second, the left-hand column of *means* was reorganized to contain only those factors viewed as antecedents to behavior (contributors to self-care): knowledge of diabetes, attitudes and perceptions towards diabetes, and attitudes towards self [self-efficacy, self-esteem]). *Self-care* was placed independently between the two end columns, contributors to self-care and patient-provider goals, to indicate its vital link particularly as associated with the desired outcome of tight metabolic control.

Figure 2. Self-Efficacy, Self-Care and Metabolic Control in Diabetes.



Adapted from "An Integrated Behavioral Medicine Approach to Improving Care of Patients with Diabetes Mellitus," by C. David Jenkins, 1995, *Behavioral Medicine, 21,* p. 61. Copyright 1995 by Behavioral Medicine. Adapted with permission of the publisher.

Although this study is primarily concerned with the relationships among self-efficacy , self-care, and metabolic control, Jenkins (1995) placed great value on the contributions of diabetes knowledge and attitudes and perceptions about diabetes (health beliefs). Therefore, a brief description of these concepts will follow so that their influence is understood.

Knowledge and Health Beliefs

Jenkins' (1995) stance on patient knowledge is supported by many fellow researchers (Bloise et al., 1997, Bradley, 1995; Day 1995; Dunn, 1990). Jenkins advocated that knowledge was sine qua non to diabetes self-care, and that diabetes education should have precedence in diabetes management. In contrast, however, Jenkins acknowledged that knowledge plays only a subsidiary role in changing and maintaining behavioral habits.

Meta-analyses have reaffirmed the value of diabetes education in diabetes management and have generally implied that increased diabetes knowledge lends to improved metabolic control (Brown 1988 & 1990; Padgett et al., 1988). However, other researchers see the fallacy of this assumption and have warned, that at times, patients with the highest knowledge level have the worst metabolic control (Bradley, 1995). Moreover, diabetes education experts have advised against a whole-hearted commitment to this generalization because insufficient definitive evidence exists to support such a conviction (Dunn, 1990).

In concert with others (Bradley, 1995; Day 1995), Jenkins (1995) spoke about the transfer of knowledge to patients in light of their health beliefs. To have impact, Jenkins strongly believed that diabetes education must be accomplished in consideration of each individual's health beliefs and perceptions. Day (1995) also recognized the importance of imparting knowledge to enhance diabetes self-care but indicated that unless a behavior change followed, the effort should be considered useless, and the goal unmet.

Bradley (1995) more thoroughly discussed the role of beliefs in knowledge acquisition. She stated that patients must not only acquire new knowledge but must embody it within their belief system to induce change and persist in this change. Bradley used Rosenstock's Health Belief Model to explain inconsistencies between knowledge level and adherence; she noted the cognitive processes that the patient undergoes before deciding which aspects of the prescribed regimen they will follow, and to what extent. The Health Belief Model (Rosenstock, Strecher & Becker, 1985) contends that a patient will weigh and balance benefits and barriers of treatment in consideration of the severity of their disease and their perceived vulnerability to the proposed disorder/complication/outcome before partaking in any new health behavior.

Rosenstock (1985) is recognized for his interest in improving compliance in chronic disease, especially diabetes. In 1985, Rosenstock proposed that the Health Belief Model be used as a conceptual model to enhance the principles of learning in diabetes education. In this article, he adamantly supported the role of self-efficacy in diabetes regimen adherence, and in later in 1985, Rosenstock et al. propounded that self-efficacy be added as the fifth concept of the Health Belief Model.

Relationships Among Self-Efficacy, Self-Care, and Metabolic Control

General Conduct of the Research

Ten published studies were identified that described the relationships among self-efficacy, self-care, and metabolic control in diabetes management; the first of these originated in 1987 (Crabtree; Grossman, Brink and Hauser; and McCaul, et al.). Of these 10 studies, five (5) explored the relationship between self-efficacy and self-care; two (2), the relationship between self-efficacy and metabolic

control; and three (3), the relationship among self-efficacy, self-care, and metabolic control.

At times, the concept of self-efficacy (Bandura, 1977b) was reviewed independently, and at other times, as an element of a psychological composite; however, self-efficacy was always discussed in light of the Social Cognitive Theory (Bandura, 1977a). Composites that embodied self-efficacy included "expectations" (McCaul, et al., 1987), "social learning factors" (Glasgow, et al., 1989), and "coping" (Rapley, 1990).

Studies were primarily conducted in outpatient settings, one of which was conducted in a camp for Type 1 adolescents (Grossman, et al., 1987). Only one study collected data that evaluated inpatients (Hurley & Shea, 1992).

Population description in these studies was often confused by inconsistent use of terminology, a well recognized problem in diabetes research and care (Glasgow, 1991). Although most authors used the terms Type 1 (juvenile onset) and Type 2 (adult onset), terms of non-insulin dependent (NIDDM) and insulin-dependent (IDDM) were also applied. The greatest confusion resulted when studies included Type 2 populations that were insulin-treated.

Using typology, populations with Type 2, or Type 1 and 2 diabetes (mixed) predominated the research. Five studies reviewed Type 2 populations, four reviewed mixed populations, and one looked specifically at persons with Type 1 diabetes (adolescents). Two studies specifically chose populations that were insulin-treated (both Type 1 and 2) (Hurley & Shea, 1992; McCaul et al., 1987).

Besides targeting people taking insulin, some investigations selected particular ethnic groups: African-American women (Skelly, Marshall, Haughey, Davis & Dunford, 1995) and Croatians (Padgett, 1991). No studies were found that examined those taking only oral hypoglycemics, or those that would be metabolically controlled by diet and exercise alone (both Type 2).

Generally, the sample size for these studies was moderate while the technique used was convenience. Sample size ranged from 62-147 with the average size 113, and the median 118. None of these studies were pilots; none mentioned study power. Nine of the studies used convenience sampling while one obtained its sample by randomly taking 10% of the clientele from each doctor-nurse team (Padgett, 1991. Two studies broke their populations out into comparison groups by diabetes type (Rapley, 1990) and gender (Grossman et al., 1987).

Inclusion and exclusion criteria were fairly uniform throughout the studies. Most limited subjects by ability to read, speak, or understand English; preset age; presence of psychological impairment or severe alcoholism; home nursing supervision; and/or pregnancy. Common diabetes-related exclusion criteria included those newly diagnosed (less than six months or a year), presence of severe disease-related complications (blindness, marked neuropathy, incapacitating renal or cardiovascular problems), or recent acute episode (diabetic ketoacidosis, hyperosmolar nonketotic syndrome, initiating hemodialysis, recovering from severe or prolonged infection). Other limiting medical problems included a recent acute illness or hospitalization from an exacerbation of another chronic condition and/or severe stroke.

Reported demographics were also fairly consistent and were used often in the analysis of the data (regression and variance associations). General demographics usually included age, gender, ethnic group, education level, socioeconomic status, marital status or presence of someone in their home, occupation, religion, and/or time spent away from their home. Diabetes-related data included type, duration of disease, regimen for control especially use of medication (insulin or oral hypoglycemics), current complications, number of

previous hospitalizations, previous diabetes education, glycated hemoglobin, and/or body mass index.

Limitations associated with the research of self-efficacy, self-care, and metabolic control were occasionally identified. Most addressed problems with self-report, particularly those pertaining to self-care measures. Glasgow (1991) recommended quantitative self-reporting where measures included type, amount, frequency or duration (e.g., diet and exercise activities) as opposed to positive/negative response-type compliance questions. At the same time, however, Glasgow (1991) noted the difficulty of performing such extensive measures and resolved that self-report questionnaires may be the most efficacious method of obtaining self-care data in smaller, less involved studies.

The influence of anti-diabetes medications and the measurement of medication-taking self-care behaviors have confounded the research of self-efficacy, self-care, and metabolic control. For these reasons, medication-related subscales have often been dropped from self-efficacy studies (Kingery & Glasgow, 1989; Padgett, 1991). Additionally, this researcher noted that many of the studies failed to address the influence of medication changes during data collection which would greatly influence post measures of metabolic control (Kavanaugh et al., 1993; Rubin et al., 1993).

Lastly, almost all studies evaluating variables that might contribute to metabolic control recognized that predicting or implying causation is a near-impossible task with this complex concept (Glasgow et al., 1989 &1992; Grossman et al, 1987; Kavanaugh et al., 1993; Padgett, 1991). However, despite the inability to draw causal conclusions, metabolic control measures (primarily glycated hemoglobin) are strongly advocated in diabetes research evaluating the influence of psychosocial variables (Glasgow & Osteen, 1992).

Measures and Instrumentation

A comparison of the 10 studies revealed that diabetes self-efficacy instruments stem from three original sources: Crabtree, McCaul et al., and Grossman et al. (all developed in 1987). Since their inauguration, all three instruments have been repeated at least once, undergone revisions, and/or been applied in different diabetic populations.

One of the first diabetes self-efficacy scales was developed by Grossman et al. (1987) and used to evaluate a group of Type 1 adolescents (IDDM). The Self-Efficacy for Diabetes Scale was a 35-item, six point Likert instrument divided into three subscales by situation (diabetes-specific, medical, and general). Subjects rated their degree of confidence from a scale of *very sure I can't do* through *very sure I can do*. Reliability and validity testing was extensively discussed.

The second diabetes-specific self-efficacy instrument was developed by McCaul et al (1987). The Self-Efficacy Scale was tested on a group of patients requiring insulin (Type 1 and 2). This scale was a 24 item, 100-point scale where subjects rated confidence in their abilities to perform a graded series of regimen behaviors in four areas (subscales): insulin injections, glucose testing, diet, and exercise. No reliability or validity testing was discussed.

In 1989, Kingery and Glasgow revised the McCaul group's Self-Efficacy Scale (1987) to better fit a Type 2 population. The original instrument was expanded from 24 to 29 items, and the scaling was change from 100 points to 200 points. The scale range now went from -100 to +100 by groupings of 10. Three of the four original subscales were kept (glucose testing, diet, and exercise). The medication subscale had proven problematic in McCaul's research (1987), and Kingery and Glasgow were unsuccessful in improving this subscale, so it was dropped.

Since undergoing modification by Kingery and Glasgow (1989), the Self-Efficacy Scale has been used repeatedly. Glasgow et al. applied the revised Self-Efficacy Scale on two other occasions (1989 & 1992). Skelly et al. used this instrument in a population of African-American, inner-city women in 1995. And although not specifically acknowledged, an Australian researcher (Kavanaugh et al., 1993) who referenced Glasgow repeatedly described a self-efficacy instrument that matched Kingery and Glasgow's.

Lastly, M. K. Crabtree, a nurse researcher completing her doctoral dissertation (1987), developed a third self-efficacy scale under the mentorship of Albert Bandura. Although mentioned in the literature (Kingery and Glasgow, 1989), her work remains unpublished but was presented at the 1987 Annual Meeting of the Society for Behavioral Medicine. Crabtree's 25-item, six point Likert Diabetes Self-Efficacy Scale (DSES) was developed for use with any diabetes population. The DSES contained four subscales: diet, exercise, medication-taking, and general self-care. The scale measured confidence in perceived abilities to perform task-specific diabetes self-care behaviors by eliciting graded responses of strongly agrees to strongly disagree. Reliability testing in a sample of 143 diabetic adults (Type 1 and 2) revealed a Cronbach's alpha of .71 for the total DSES with the subscale alphas as follows: diet (8 items) = .77, exercise (6 items) = .60, medication-taking (7 items) = .65, and general diabetes management (4 items) = .56.

Padgett (1991) validated Crabtree's DSES crossculturally in a population of Croatians from Zagreb, Yugoslavia. Her population was described as "noninsulin dependent," which is indicative of Type 2 diabetes, but she did not further clarify the use or nonuse of oral hypoglycemics. Padgett's only modification to the DSES was the deletion of the medication subscale for reasons similar to those mentioned by Kingery and Glasgow (1989) and because Crabtree (1987) had reported a modest alpha coefficient (0.65) for this subscale.

In 1992, Hurley and Shea modified Crabtree's DSES (1987) and made the instrument specific for insulin treated diabetic patients (both Type 1 and 2). The Insulin Management Diabetes Self-Efficacy Scale (IMDSES) was a 28-item, six point Likert scale with three subscales of diet, exercise, and insulin. Responses reflected an individual's abilities to perform insulin-dependent diabetes self-care and ranged from strongly agree to strongly disagree. Reliability and validity testing was extensively reported and included the development of a one-to-one corollary to the IMDSES, the Insulin Management Diabetes Self-Care Scale (IMDSCS), for convergent validity verification (Hurley, 1990).

Self-efficacy measures were frequently employed with measures of self-care and/or metabolic control (glycated hemoglobin). Instrumentation among studies varied little: measures were either administered together and only once, or administered initially and repeated over time. Analysis of the data varied from simplistic evaluations of correlations to complex comparisons made by five or six different statistical applications per study.

Five of the studies completed all their measures once (Crabtree, 1987; Grossman et al., 1987; Hurley & Shea, 1992; Padgett, 1991; and Rapley, 1990). Analysis was then conducted on the interrelationships among the variables, demographics, and disease-related data. Hurley and Shea (1992), measured self-efficacy upon discharge from an inpatient program, then measured self-care three weeks later. In general, these studies analyzed their data by intercorrelation, multiple regression, stepwise multiple regression, bivariate analysis, and multivariate analysis.

The other five studies repeated all measures over time reviewing the stability of the variables (Glasgow et al., 1989; Kavanaugh et al., 1993; Kingery & Glasgow, 1989; McCaul et al., 1987, and Skelly et al., 1995). These studies generally conducted an initial measure, then repeated their measures one or more times

again in the next two months to one year. In addition to the previously mentioned statistical analyses, these studies often incorporated t-test, repeated measure analysis of the variance, and analysis of the covariance.

If comparisons of glycated hemoglobin were made, the time span between measures ranged from two months (Kavanaugh et al., 1993) to six months. Because the definition for glycated hemoglobin typically describes a 100-120 day window for accurately assessing complete change in this physiological measure (Pagana & Pagana, 1995), the validity of Kavanaugh's findings at two months were questioned.

Findings

In the last ten years, research of self-efficacy, self-care, and metabolic control has moved from linking these variables to investigating their predictive nature (self-efficacy toward self-care, and metabolic control and self-care toward metabolic control). Findings from the 10 studies that address these relationships are discussed in groupings as follows: self-efficacy and self-care (5), self-efficacy and metabolic control (2), self-efficacy, self-care, and metabolic control (3).

Self-Efficacy and Self-Care

Generally, these five studies were conducted for two purposes: (1) to test Bandura's self-efficacy theory which proposes that perceived self-efficacy is a determinant behavior (verifying the proposed direction of the relationship) and (2) to describe the strength of the relationship between perceived self-efficacy and self-care behaviors. Prior to this, diabetes outcome research focused on issues of self-care compliance as related to metabolic control.

McCaul et al. (1987) was one of the first to examine self-efficacy and did so under the composite of *expectations*. Expectations was one of four predictor variables reviewed in a population of 107 insulin-treated subjects (Type 1 and 2). Two measures, separated by six months, were conducted. The expectation

composite was evaluated by multi-method adherence (self-care) measures in four areas: insulin injections, glucose testing, diet, and exercise. Through regression analysis, expectancies were demonstrated to be stronger predictors of adherence than knowledge or skills; self-efficacy was the only variable associated with every regimen outcome concurrently and prospectively. Self-efficacy was found to be a stronger predictor of insulin administration and glucose testing adherence than of diet and exercise adherence.

In 1989, Kingery and Glasgow revised McCaul's Self-Efficacy Scale and applied this measure to a group with Type 2 diabetes ($n = 127$) in the same manner (two measures separated by six months). Diet, exercise, and glucose testing were examined as adherence variables; the medication subscale proved problematic and was dropped. Kingery and Glasgow's findings were opposite of McCaul et al. (1987): multiple regression demonstrated that self-efficacy was a greater predictor of exercise adherence (especially in females) than of adherence to diet or glucose testing. However, the strength of self-efficacy's relationship to self-care varied over the duration (diet, $r = .04$ & $.22$; exercise-male, $r = .37$ & $.30$; exercise-female, $r = .44$ & $.45$; glucose testing, $r = .21$ & $.21$; all at $p < .05$). Kingery and Glasgow concluded that self-efficacy should be assessed in any health evaluation (in a task-specific manner), and that weak areas should undergo self-efficacy enhancement so that adherence to the diabetes regimen might improve.

Using the Self-Efficacy Questionnaire, as revised by Kingery and Glasgow (1989), Skelly et al. (1995) examined a population of inner-city, African-American, Type 2, diabetic women in two measures separated by 4-5 months. Self-efficacy scores and adherence ratings were greater for medication taking and glucose testing than for diet and exercise. Bivariate analysis confirmed self-efficacy's relationship to self-care but showed variation in the regimen relationships over time: glucose testing = variance 18%, then 18%, exercise = variance 53%, then 29%,

and diet = variance 24%, then 0%. Multiple regression mimicked these results demonstrating that self-efficacy was significant for diet and exercise at Time 1, and for glucose testing and exercise at Time 2 ($p < .05$). Conclusions confirmed self-efficacy's relationship to self-care but that the strength of this relationship varied at different points in time, particularly for diet and exercise behaviors. Recommendations were to assess self-efficacy frequently and to focus support and self-efficacy enhancement efforts on the more difficult, less stable regimen behaviors of diet and exercise.

Another instrument, the Diabetes Self-Efficacy Scale (DSES) (Crabtree, 1987), further validated the predictive quality of self-efficacy as related to self-care. Although unpublished, an abstract stated that this study was conducted in a population of Type 1 and 2 persons with diabetes ($n = 143$); all measures were completed once. Bivariate analysis demonstrated that self-efficacy explained 25-35% of the variance in diet, exercise, and general diabetes self-care after controlling for the effects of age, sex, marital status, diabetes type, duration, severity, and number of complications. Crabtree also noted that social support was not shown to be significantly related to self-efficacy or self-care.

Hurley and Shea (1992) developed their Insulin Management Diabetes Self-Efficacy Scale and Insulin Management Diabetes Self-Care Scale from Crabtree's (1987) DSES. Their efforts centered on insulin-treated patients ($n = 142$) participating in a 5-day, inpatient, intensive, diabetes management program; each measure was completed only once: self-efficacy at discharge and self-care three weeks later. Through a microanalytic correlational match, Hurley and Shea were able to show a strong relationship between the total scores ($r = .578$, $p < .001$) and subscale scores (general, $r = .398$, diet, $r = .37$, insulin, .67; all at $p < .001$) of the two instruments. Multiple regression eliminated all of the diabetes-related or demographic variables as significant predictors for self-care and demonstrated

that self-efficacy alone accounted for 33% of the variance in self-care behaviors. Like Kingery and Glasgow (1989), Hurley and Shea recommended that self-efficacy enhancement become an essential component of diabetes education to increase independence, improve confidence, and promote adherence.

Self-Efficacy and Metabolic Control

Only two studies were identified that evaluated just self-efficacy and metabolic control. One of these studies used a HbA1c while the other used other metabolic measures. Grossman et al. (1987) found a significant relationship between self-efficacy and metabolic control, but Rapley (1990) did not.

Grossman et al. developed the Self-Efficacy in Diabetes (SED) instrument in 1987 and applied this measure to a group of Type 1 adolescents ($n = 68$) at a diabetes summer camp. All measures were collected only once, but four indices of metabolic control were collected over a 4-day period (average blood sugar, urine glucose levels, urine acetone, and 24-hour glycosuria testing). Grossman's group recognized that the HbA1c was a better measure of adherence, but this test was unavailable at the camp. Overall correlations for self-efficacy to metabolic control showed a significant relationship for total self-efficacy ($r = .25$, $p < .05$) and dietary-related self-efficacy ($r = .25$, $p < .025$) while correlations for these variables among girls were observed as stronger (total $r = .40$, $p < .01$; diet $r = .39$, $p < .01$). Despite these findings, Grossman et al. offered multiple reasons why the study could not imply causation.

An Australian nurse researcher (Rapley, 1990) tested the assumed predictive nature of self-efficacy, hardiness, coping style, and psychosocial adaptation in relation to metabolic control. Rapley conducted her study in a mixed Type 1/Type 2 population ($n = 97$), completing all measures once. Rapley assessed self-efficacy using a general self-efficacy scale developed in 1982 by Sherer. Because of this, however, her findings remain questionable since, according Kingery and Glasgow

(1989), global measures of self-efficacy are inadequate in describing this concept in this population (diabetes-specific self-efficacy instruments must be used). With this in mind, findings showed that only in the metabolically controlled Type 1 group (IDDM) was higher self-efficacy significantly correlated with the HbA1c (r = -.314 [standard deviation, and significance level not identified]) while multiple regression analysis did not identify self-efficacy as a significant predictor of metabolic control. Only hardiness and psychosocial adjustment were found to be significant predictors of metabolic control.

Self-Efficacy, Self-Care, and Metabolic Control

Three studies were identified that reviewed self-efficacy, self-care, and metabolic control; two used Kingery and Glasgow's instrument (1989). The existence and strength of inter-relationships varied greatly, especially in regards to the subscale assessed (diet, exercise, glucose monitoring, medication-taking, etc). In general: (1) diet and exercise elicited the lowest self-efficacy scores, (2) self-efficacy demonstrated the greatest predicative value for diet and exercise self-care, and (3) self-efficacy was only predictive of metabolic control in one study while self-care was predictive of metabolic control in two studies.

Glasgow et al. (1989) conducted the first study evaluating the relationships among these three variables. Here again, the Self-Efficacy Scale that he and Kingery (1989) revised was put to use on a Type 2 diabetic population (n = 127) in two measures, six months apart. Self-efficacy was encompassed in the composite of "beliefs/expectations" as one of four social learning values under predictive investigation (knowledge, skills, and environmental support). Multi-method measures of self-care were grouped into composites for evaluation of diet, exercise, and glucose testing. Self-efficacy scores were highest for medication-taking, then glucose testing, while diet self-efficacy was third, and exercise self-efficacy last. Preliminary analysis showed that regimen adherence could not be

generalized, so multiple regression was used to examine the relationship of self-efficacy to specific regimen behaviors as proposed by the Social Cognitive Theory. Similar to McCaul et al., multiple regression showed that the social learning variables predicted self-care beyond that which was attributed to demographics. Bivariate correlation demonstrated that the belief/expectations composite was a strong predictor of level of exercise ($r = .40$, $p < .001$) but weakly associated with glucose testing ($r = .09$, $p < .10$) and diet ($r = .15$, $p < .05$). Multiple regression revealed a fairly strong relationship between the exercise self-care, and metabolic control ($r = .24$, $p < .01$); however, the direction of the relationship was counterintuitive (as exercise is increased, HbA1c should decrease). Recommendations were to shift the focus of diabetes education from the more medically oriented diabetes self-care behaviors (glucose testing and medication-taking) toward those associated with lifestyle changes (diet and exercise).

The most recent study reviewing all three variables was completed in Australia by Kavanaugh et al (1995). Kavanaugh did not credit the instrument he used, but the instrument's description matched Kingery and Glasgow's Self-Efficacy Scale (1989), and Kavanaugh repeatedly referenced their work. This group chose to explore the predictive relationship of self-efficacy versus past adherence on self-care, and metabolic control. Two measures separated by two months were taken in a mixed population of those with Types 1 and 2 diabetes ($n = 63$). Stepwise multiple regression demonstrated that premeasures of self-efficacy cancelled out the predictive effect of past adherence for diet and exercise and was significant for glucose testing. Further analysis showed the strength of self-efficacy's predictive value was greater for diet (change in R squared $= .168$, F change $= 18.19$, $p < .001$) than in glucose testing (change in R squared $= .054$, F change $= 6.09$, $p < .02$) and exercise (change in R squared $= .067$, F change $= 5.92$, $p < .02$). Concurrent correlations of adherence (self-care) and the HbA1c were significant ($p < .01$), and

stepwise multiple regression adding diabetes treatment type, then demographics, showed that adherence accounted for 16.7% and 11.1% of the variance respectively. Prediction of post HbA1c from pretest variables through stepwise multiple regression showed that self-efficacy remained significant even after entry of pretest HbA1c and treatment type. Entry of demographics into the equation left only dietary self-efficacy significant ($p < .05$). Again, comments were offered pertaining to the complexity of one's HbA1c and the fact that self-efficacy and self-care were merely partial contributors that were only indirectly linked. Conclusions reiterated that self-efficacy was a stronger predictor of diet and exercise regimen adherence and that self-efficacy enhancement interventions should concentrate on these more problematic areas of self-care.

A final, but differently instrumented research effort of self-efficacy, self-care, and metabolic control came from Padgett (1991). This researcher cross-culturally validated Crabtree's 1987 DSES (excluding the medication subscale) in a non-insulin dependent Yugoslavian population ($n = 147$). Padgett completed all measures once and evaluated the relationships between self-efficacy, depressive symptoms, demographics, disease-related data, and self and physician-rated adherence. Self-efficacy scores for diet and general care were nearly the same and above the scores derived for exercise self-efficacy. Correlational analysis further validated self-efficacy's relation to self-care ($r = .40$, $p < .01$), and multivariate analysis showed that self-efficacy explained 33% of the variance in self-care. An almost nonexistent relationship was noted between self-efficacy and metabolic control ($r = .02$). The relationship of self-care to metabolic control was also weak ($r = .05$, $p < .01$), and Padgett readily commented on the inability to predict metabolic control because its complex nature. Bivariate analysis revealed significant relationships between self-efficacy and demographics (higher self-

efficacy for males, younger age, and higher educational level) than had been found previously.

Self-Efficacy Enhancement: Pre and Post Interventional Measure

Efforts to evaluate diabetes self-efficacy enhancement interventions have been minimal. Only three studies were found that chose to evaluate the possibility of self-efficacy enhancement through a diabetes educational intervention; these studies did not examine variable interrelationships (Glasgow, Toobert, Hampson, Brown, Lewinsohn & Donnelly, 1992; Rubin et al., 1989 & 1990), and those studies conducted by Rubin et al. reviewed the same program. All three studies involved pre and post measurements around intensive, outpatient, multidisciplinary diabetes education/management programs that focused on improving problem-solving and coping skills in self-care.

Both of Rubin's studies (1989 & 1993) used an adult version of Grossman's Self-Efficacy in Diabetes Scale (1987) to evaluate pre and post educational intervention self-efficacy. Rubin's 1989 study included measures of self-efficacy, self-care, and metabolic control in a mixed diabetes population (Types 1 and 2; $n = 124$). Self-efficacy was encompassed within the composite of "emotional well-being" with self-esteem, anxiety, and depression. Data was gathered pre and post program, and at six months. Self-efficacy rose significantly at the post program measure (113.4 ± 1.4 to 124.8 ± 1.3, $p < .001$) and decreased only insignificantly at the six-month follow-up (121.8 ± 1.4, $p < .001$). Self-care was measured preprogram and at six months. Significant improvements were seen in all four behaviors (insulin-adjustment, bingeing, exercise, blood-glucose monitoring). Patients' HbA1c measures significantly improved from preprogram to six months ($11.5\% \pm 0.4\%$ to $9.5\% \pm 0.3\%$, $p < .001$). A unique finding was that those considered in worst control

preprogram changed the most, where those classed as in the best control preprogram showed little change in any of the measures.

Rubin's 1993 study reviewed only self-efficacy but conducted measures over a greater time span (preprogram, at six months, and at one year). Findings demonstrated that self-efficacy increased post-program and was maintained over a year's time (113.7$\pm$17.2; 123.0$\pm$16.2; 123.6$\pm$16.2; all at $p < .001$). Rubin et al. (1993) recommended that self-efficacy enhancement be incorporated into all diabetes education efforts. To this, Rubin's group added their supposition that the relationship between self-efficacy and self-care behaviors was cyclical in nature: enhanced self-efficacy lead to improved self-care, which further enhanced one's confidence in his ability to perform the skills (mastery), which further increased one's self-efficacy toward those skills, etc.

Glasgow et al. (1992) evaluated a 10-session diabetes education program (as described above) for a population of diabetic persons over age 60 (Type 2; $n = 102$), and although self-efficacy scores did not change, self-care behaviors and metabolic control did. This group used McCaul's (1987) revised Self-Efficacy Scale (Kingery & Glasgow, 1989) and applied this instrument with measures of self-care, and metabolic control. Measures were conducted in randomly selected immediate and delayed treatment groups, at pre and post program (3 months), and then at six months. Only change over time was evaluated since these researchers consider self-efficacy predictive of self-care (Glasgow et al., 1989; Kingery & Glasgow, 1989; McCaul et al., 1987). Findings for both groups were closely replicated, but generally, the immediate treatment group demonstrated significant reductions in caloric and fat intake, as well as weight, and showed an increase in the frequency of glucose monitoring (all maintained at 6 months). Improvements in the amount of exercise were not seen until the six month measure. HbA1c's significantly decreased for both groups in the pre and post measures (no medication changes

were made) while analysis of the covariance for HbA1c revealed a significant effect in favor of the intervention ($F = 3.23$, $df = 1, 90$, $p < .08$). A more significant change in the HbA1c was seen in those not treated with insulin, as compared to those who were being treated but not undergoing any medication manipulation during the study. Comments were made pertaining to the complexity of the metabolic measure and the inability to draw causal conclusion from this data. Self-efficacy scores did not change over time, but this was attributed to a ceiling effect caused by high preprogram scores.

Summary

Self-efficacy has demonstrated its importance in both health-related and non-health-related fields. However, the exploration of self-efficacy in diabetes is a fairly recent and is of minimal amount. In contrast, diabetes self-care has been examined for years but has been troubled by inconsistent methodologies and unreliable measures. The glycated hemoglobin has been dubbed a reputable measure of metabolic control since the mid 1980s, and is a standard of care in diabetes evaluation.

Research exploring the predictive nature of self-efficacy toward self-care has generally supported Bandura's Social Cognitive Theory and theory of self-efficacy, but is confusing. Self-efficacy appears to predict self-care, but only does so subscale-specific evaluations. Second, diet self-efficacy and exercise self-efficacy appear to have the greatest predictive value toward self-care, but typically demonstrate the lowest self-efficacy scores. Third, researchers have noted that diet and exercise behaviors are the most difficult to change and maintain (Glasgow, 1991).

Additionally, research examining the relationships of self-efficacy to metabolic and self-care to metabolic control has been varied; however, metabolic

control is a complex factor known to inhibit implications of causality. Nevertheless, researchers that investigate the influence of psychosocial factors in diabetes management advocate glycated hemoglobin evaluation to demonstrate variable association.

Nearly all diabetes studies reviewed recommended self-efficacy enhancement through diabetes education, yet few studies have been conducted on programs that have attempted to do such. Additionally, no studies were found that investigated self-efficacy in Type 2 populations controlled solely by diet and exercise.

In conclusion, a study incorporating the variables of self-efficacy, self-care, and metabolic control would offer further support for the role of psychological variables in diabetes management and help clarify relationships among these concepts. Investigating these variables in a population of persons with Type 2, diet and exercise controlled diabetes who have been selected to undergo a diabetes education program would: (1) remove the medication-taking limitations known to confound these studies, (2) yield information from a group not previously examined, (3) provide insight to a diabetes education program attempting to enhance self-self-efficacy, and (4) describe self-efficacy 's role in a group that relies solely on the most difficult self-care behaviors---diet and exercise.

III. METHOD

The purposes of this study were: (1) to describe the relationships among self-efficacy, self-care, and metabolic control and (2) to examine the difference between pre and post treatment measures of self-efficacy, self-care, and metabolic control. The target population was persons with Type 2, diet and exercise controlled diabetes; the treatment was an outpatient, integrated, multidisciplinary diabetes educational intervention.

Research Design

A one-group pretest-posttest design was employed to examine the variables of self-efficacy, self-care, and metabolic control. The intervention was a month-long, outpatient, integrated, multidisciplinary diabetes education program entitled the Diabetes Patient Education Program (DPEP). Two Diabetes Patient Education Programs were assessed: November 1997 and December 1997. Post measures were conducted four months after the completion of each diabetes education program.

Setting

The study was approved by the Institutional Review Board of the 74th Medical Group, Wright-Patterson Air Force Base and the Office of Research and Sponsored Programs, Wright State University, both in Dayton, Ohio (Appendix E). The study was then initiated in an outpatient clinic of this 156-bed tertiary military medical center in southwest Ohio.

The Diabetes Patient Education Program (DPEP) is taught primarily in the Department of Internal Medicine and supports all outpatient diabetes education for this facility. The DPEP is administered under the guidance of the Chief of Endocrinology, Diabetes, and Metabolism but is the primary responsibility of the Diabetes Care Nurse Specialist who is a registered nurse (RN), certified diabetes educator (CDE), and full-time civilian employee. A second, part-time RN, CDE, and United States Air Force (USAF) Individual Mobilization Augmentee (IMA) is present in the diabetes clinic approximately two days per week.

The DPEP is categorized as an *enhanced* educational effort (Padgett, 1988). The group-taught program is conducted in a moderately structured manner by a team of specialists that offers individual counseling as needed. The DPEP is holistically focused and provides not only diabetes education, but also psychosocial support to facilitate behavioral change. The program's integrated multidisciplinary staff includes a certified diabetes educator, an endocrinologist, a physical therapist, a registered dietitian, a podiatrist, and a psychologist (Appendix C).

A Diabetes Patient Education Program occurs monthly and consists of eight topic-specific classes. Instruction consistency is maintained through detailed teaching plans. If a participant requires instruction beyond what is provided in class, a CDE will provide one-to-one education based on the standards of the American Association of Diabetes Educators. The DPEP complies with National Diabetes Advisory Board standards endorsed by the diabetes community.

Population

The population targeted was persons with Type 2, diet and exercised controlled diabetes. The accessible population was derived from patients referred to the November 1997, December 1997, and January 1998 Diabetes Patient

Education Programs. Thirty-four participants had Type 2, diet and exercise controlled diabetes: 16 from the November program, 7 from the December program, and 11 from the January program.

Sample

The sample was obtained by convenience. Potential subjects were notified by mail of their qualification for the study prior to the start of their Diabetes Patient Education Program. All study candidates received a cover letter, *Notification of Selection for Research Study* (Appendix F), with their DPEP orientation packet.

Potential subjects were called one week after the cover letter was sent. The purpose of this phone call was to: (1) answer questions about the study, (2) assess willingness/non-willingness to participate, and (3) ensure that the subject's understood that the researcher had received permission from the hospital to access their medical records and information stored in the hospital computer data should they decide to participate (Appendix E). Those that agreed to participate were instructed to come two hours prior to the start of their first DPEP class and informed that their data could not be included if they missed one DPEP class.

From the three programs assessed, only 7 of the 34 potential subjects (20.5%) agreed to participate. Six of the subjects partook in the November DPEP and one subject participated in the December DPEP; none of the potential subjects registered for the January 1998 DPEP chose to be in the study.

After verbal consent was provided by the subjects, medical records and information stored in the hospital computer were accessed; exclusion criteria were applied and demographic and diabetes-related data collected. Subjects were to be notified if exclusion was necessary prior to their first DPEP class (and

researcher's premeasure meeting), however, no exclusion criteria applied.

Exclusion criteria included:

1. Age less than 18 years
2. Non-English reading
3. Presence of a debilitating diabetes sequelae (blindness, severe neuropathy, incapacitating renal or cardiovascular disease)
4. Current state of acute diabetes instability (hyperglycemic hyperosmolar nonketotic syndrome, severe infection, initiating dialysis)
5. Pregnancy
6. Presence of factors known to affect glycated hemoglobin measures that are not correctable by laboratory processing: recent acute blood loss and presence of hemolytic anemia. These factors were also assessed at post measure since their occurrence during the pre and post measure interim (4 months) could greatly affect study findings:
   A. Recent Major Blood Loss:
      - Approximating 450 mls in the previous 30 days
   B. Hemolytic Anemias:
      - Genetic Disorders of the Red Cell
        - Membrane
          - Hereditary spherocytosis
          - Hereditary ovalocytosis
          - Stomatocytosis
          - Pyropoikilocytosis
          - Other "leaky" membrane disorders
          - March haemoglobinuria
          - Acanthocytosis

- Haemoglobin
  - Sickling disorders
  - Haemoglobins C, D, and E
  - Unstable haemoglobins
  - Thalassaemia syndromes
- Energy Pathways
  - Hexose-monophosphate shunt
  - Embden-Meyerhof pathway
  - Others

- Acquired Disorders of the Red Cell
  - Immune
    - Isoimmune; Rh or ABO incompatibility
    - Autoimmune; warm of cold antibodies
  - Non-immune
    - Trauma
      - Microangiopathy
      - Valve prosthesis
      - Body surface
    - Membrane defects; PNH [paroxysmal nocturnal haemoglobinuria], liver disease
    - Parasitic disorders
    - Bacterial infection
    - Physical agents, drugs, and chemicals
    - Hypersplenism
    - Defective red cell maturation

Nonparticipants

Diabetes outcome research has notoriously failed to describe nonparticipants (Glasgow et al., 1996), however, rationale for nonparticipation was assessed in this study. A general statement regarding the reason for research non-participation was obtained from 22 of the 28 nonparticipants.

The information obtained suggested that DPEP class attendance was more of a concern than study participation; only four potential candidates actually refused to partake in the study. Rank-ordered (most common to least common) categorical responses related to DPEP class nonattendance were as follows: (1) conflicting work schedule, (2) other life priorities (illnesses of family and friends; church activities; and holiday shopping, visitors and activities). (3) inconvenient class times, (4) lack of transportation, (5) disbelief that the person had diabetes or that an actual diagnosis of diabetes had been made (6) distance from hospital, and (7) previous diabetes education. All nonparticipants were offered a one-to-one diabetes education session with the researcher; only 2 of the 22 partook.

Attrition

Only one subject chose not to complete the study; this subject's data was excluded from analysis. None of the remaining subjects (n = 6) met parameters for data exclusion: (1) no anti-diabetes medications were initiated during the study, and (2) all subjects attended every Diabetes Patient Education Program class.

Human Subject Protection

Subjects participating in this study were made well aware of the research, its purpose, its processes, and their role. First, subjects received an explicit cover letter entitled *Notification of Selection for Research Study* (Appendix F). Second, the study and its requirements were reviewed verbally during the cover letter follow-up phone call. Lastly, although considered a minimal risk study (Burns &

Grove, p. 112, 1993), the Institutional Review Board of the 74th Medical Group, Wright-Patterson Air Force Base, Dayton, Ohio requested a signed informed consent (Appendix E). Thus, the study was again reviewed before the consent form was signed (Appendix F).

Specifically, the cover letter addressed self-determination, selection, privacy, confidentiality, and risks and benefits (Burns & Grove, 1993, pp. 105-107). Fairness of selection was maintained by convenience sampling of a selected target group. The right to self-determination was described, and subjects were informed that a non-participatory decision would not affect the care they were to receive.

Privacy was protected by: (1) notifying subjects that this active duty Air Force nurse officer and researcher had permission to access their medical records and information stored in the hospital computer database (Appendix E), and then (2) allowing subjects the opportunity to refuse the researcher access to this information. Additionally, subjects were informed that the information obtained from these sources would not exceed that which was necessary to complete screening for exclusion criteria and the *Personal Information Data Sheet* (demographics) (Appendix B), and that privacy would be sustained in accordance with the 1974 Privacy Act.

Confidentiality was maintained by enacting a numerical coding system that linked the data to the subjects. The master coding list, demographic sheet, questionnaires, and lab results were locked in a fire-safe box at the researcher's home; the researcher had the only key.

Risks and discomforts were primarily associated HbA1c evaluation, however, every effort was made to minimize risks and discomfort and provide a clinically appropriate evaluation of metabolic control. First, evaluation of the HbA1c is considered a standard in diabetes care; evaluation usually occurs upon diagnosis and is recommended *quarterly* for those undergoing change in therapy or those

with poor glycemic control (ADA, 1997 b & c). Second, the selected timeframe for HbA1c post-measure analysis (120 days from premeasure) was based on the literature which stated that a 90 to 120-day lapse post intervention provides the most efficacious reflection of treatment effect (Kolaczynski & Goldstein, 1997). Third, the laboratory test in and of itself was considered minimal (Burns & Grove, 1993, p. 112) because risks for this procedure were no greater than that associated with other routine lab work (echymosis, hematoma, bleeding, thrombosis, thrombophlebitis, or infection). Fourth, the researcher established parameters in accordance with the literature to avoid unnecessary phlebotomy where possible (Goldstein, et al., 1995; Kaplan & Pesce, 1996; Kolaczynski & Goldstein, 1997): the HbA1c was not to be drawn if a subject had a posted HbA1c, the test had been done within two of the established pre/post measure date, and the test had been processed in the facility's laboratory. Fifth, boronate affinity chromatography is recognized as optimal method for performing HbA1c analysis (Davidson, 1991; Garlick et al., 1983; Kolaczynski & Goldstein, 1997). Sixth, the laboratory processing the HbA1c demonstrated quality control through national accreditation, regulatory and manufacturer guideline compliance, and internal operating instructions standards (Appendix D). Seventh, clinical accountability for the HbA1c was maintained by listing the endocrinologist as the provider of care (Appendix E). Lastly, subjects incurred no charge for this laboratory test because they were all military beneficiaries.

Individually, the subjects reaped no benefits. Globally, diabetes care knowledge was enhanced through the description of psychosocial variables that influence diabetes outcomes. More specifically, insight was gained as to how the Diabetes Patient Education Program effects self-efficacy, self-care and metabolic control in its diet and exercise controlled, Type 2 diabetes population.

Measurements

The Insulin Management Diabetes Self-Efficacy Scale (IMDSES)

A modified version of Hurley's (1990) Insulin Management Diabetes Self-Efficacy Scale (IMDSES) (Appendix A) was used to operationalize self-efficacy in a Type 2 population that controls its diabetes by diet and exercise. The researcher was granted permission to modify this instrument (Appendix E). The modified version was renamed the *Nonmedication-Taking Diabetes Self-Efficacy Scale (NMTDSES)* (Appendix B).

The IMDSES was developed in 1990, by Ann Hurley, a US Army Reserve Colonel and Associate Director for Education and Program Evaluation, Geriatric Research Education and Clinical Center of the Edith Nourse Rogers Memorial Veterans Hospital in Bedford, Massachusetts. The IMDSES is a revised rendition of Crabtree's (1987) well-tested Diabetes Self-Efficacy Scale (DSES) (see Chapter 2). Hurley increased item specificity, ensured items reflected only self-efficacy, and directed the instrument towards those who use insulin.

The Insulin Management Diabetes Self-Efficacy Scale underwent extensive reliability and validity testing. First, Hurley modified content domain using the well-recognized Diabetes Teaching Guide of the Joslin Diabetes Center. Next, three diabetes nurse educators served as content specialists while five patients reviewed and edited the instrument for understanding and clarity. Finally, six self-efficacy judges rated items for conceptual distinction, relevance, and clarity. Content validity was declared beyond a .05 level of significance.

To ensure convergent validity, Hurley (1990) administered a one-to-one corollary diabetes self-care scale and obtained a glycated hemoglobin for correlation. This Insulin Management Diabetes Self-Care Scale (IMDSCS) then underwent simultaneous reliability and validity testing which will be discussed in the next section.

Empirical testing was conducted in two phases. In phase I, retest stability was evaluated by a convenience sample of 27 out of 38 outpatient responders. Evidence for instrument stability was provided by Pearson correlation ($r = .58$, $n = 25$, $p < .002$) while paired *t* tests, $t(24) = .59$, $p < .56$, revealed that the scale means and variance were unchanged from test ($M = 4.95$) to retest ($M = 5.01$) (Hurley, 1990).

In phase 2, the same data was collected on 89 inpatients. Information from both samples were compared and then combined ($n = 127$). Convergent validity and preliminary factor structure were then evaluated. Factor analysis revealed nine factors with eigenvalues greater than or equal to one and that explained 69% of the variance. A theta coefficient of .87 was obtained from the first factor eigenvalue. Five of the factors were interpreted and labeled (Hurley, 1990).

No differences were found in final comparisons of total and subscale scores between the inpatient and outpatient groups. Internal consistency of the combined sample ($n = 79$) revealed a Cronbach's alpha of .82 for the total Insulin Management Diabetes Self-Efficacy Scale, and subscale alphas were as follows: general (6 items) = .68, diet (7 items) = .78, insulin (11 items) = .62 (Hurley, 1990). Discriminant analysis was then conducted during Hurley and Shea's 1992 research effort; two insulin items were removed that demonstrated low power.

The final and current IMDSES is described as an insulin-specific, 28-item, six-point Likert scale questionnaire with responses ranging from 1-strongly agree to 6-strongly disagree with a *not applicable* category available. The IMDSES reflects seven types of diabetes behaviors: (1) general, (2) diet, (3) exercise, (4) foot care, (5) monitoring, (6) insulin administration, and (7) detecting, preventing, or treating high or low blood glucose reactions. The behaviors are clustered into the three subscales of general, diet, and insulin with four additional items (two exercise; two foot care). Cronbach's alpha for the total Insulin Management

Diabetes Self-Efficacy Scale is reported at .86, with the subscales reported as follows: general = .67 (6 items), diet = .78 (7 items), and insulin = .77 (9 items) (Hurley & Shea, 1992).

Because this study's diabetes population was not insulin-treated (controlled by diet and exercise alone) the insulin subscale was dropped. However, three items that pertained to blood glucose monitoring were maintained, but a new subscale was not created since a factor analysis was not performed (Munro & Page, 1993). The instrument was renamed the *Nonmedication-Taking Diabetes Self-Efficacy Scale (NMTDSES)*. Thus, twenty items from the original scale remain: six general (items 1, 2, 3, 4, 27, 28), seven diet (items 5, 6, 7, 8, 9, 10, 11), two foot care (items 14 & 15), two exercise (items 12 & 13), and three monitoring (items 16, 17, and 18 taken from insulin subscale). Only original items 27 and 28 were renumbered, 19 and 20, in the modification process.

Scoring of the NMTDSES was conducted as described by Hurley (1990). Of the items kept, fourteen were positively worded (1, 2, 5, 6, 7, 10, 11, 12, 14, 15, 17, 18, 27 [19], and [28]) and were reverse scored, so that higher scores equate to a higher levels of self-efficacy. Scores were based on the one-to-six range of Likert responses with the *not applicable* category coded as missing data. Total and subscale scores were summed, and the mean computed. Subscale means (general and diet) were figured if two items were left unanswered, and total means calculated if at least 15 of the 20 items were answered. Surveys that exceeded the aforementioned parameters for missing data were to be only used in frequency calculations; however, no NMTDSESs from this study met these parameters. Reliability results will be discussed under data analysis.

The Insulin Management Self-Care Scale (IMSCS)

Self-care was operationalized by Hurley's (1990) one-to-one corollary to the IMDSES, the Insulin Management Diabetes Self-Care Scale (IMDSCS) (Appendix A). The

IMDSCS's development and reliability and validity testing will only be briefly discussed since the IMDSCS mirrors the Insulin Management Diabetes Self-Efficacy Scale (IMDSES).

As with the IMDSES, authorization was obtained to modify the IMSDCS to best suit a population of persons with Type 2, diet and exercise controlled diabetes (Appendix E). The modified version was renamed the *Nonmedication-Taking Diabetes Self-Care Scale (NMTDSES)* (Appendix B).

The development of the IMDSCS as an item-for-item corollary to the IMDSES was supported by Bandura's Social Cognitive Theory. The Social Cognitive Theory proposes a microanalytic match between efficacy and behavior (Bandura & Adams, 1977). Thus, self-care is the fulfilled behavior for which an individual demonstrated some level of self-efficacy, and while the IMDSCS asks *Did you...?*, the IMDSES asks *Can you...?*.

The 28-item Insulin Management Diabetes Self-Care Scale was piloted along with the IMDSES in the previously mentioned 127 subjects. Reliability tests for the total IMDSCS revealed a Cronbach's alpha of .96 (n = 48) while subscales fared as follows: (1) general = .91 (6 items, n = 120), (2) diet = .92 (7 items, n = 110), and (3) insulin = .88 (11 items, n = 92). Retest stability of the IMDSCS showed that it was a stable measure (r = .859, n = 27, p = .000) and that means were unchanged from test (M = 4.84) to retest (M = 4.86) 22 days later, t (26) = 0.32, p = .751 (Hurley, 1990). As would be expected, the previously discussed analysis (Hurley & Shea, 1992) recognized the same low discriminant power items on this scale, so they were removed.

The final, and current, version of the IMDSCS (alpha = .90) is an insulin-specific, 26-item, six-point Likert scale corollary to the IMDSES with three subscales: general (6 items, alpha = .80), diet (7 items, alpha = .81), and insulin (9 items,

alpha = .79). Two exercise and two foot care items are also included (Hurley, 1990; Hurley & Shea, 1992).

As with the IMDSES, the IMDSCS has been modified to fit the target population. Changes made mirrored those described in the IMDSES section. A 20-item, one-to-one corollary to the NMTDSES resulted, and was named the *Nonmedication-Taking Diabetes Self-Care Scale (NMTDSCS)*. Scoring was completed as previously discussed; positively worded items that were reversed scored included 1, 2, 3, 5, 6, 8, 10, 12, 15, 16, 17, and [19]. Again, no missing data parameters were met. Reliability testing was completed and will be discussed under data analysis.

Metabolic Control

A percent glycated hemoglobin (HbA1c) was used to measure metabolic control. The initiation and timing of this test was based on the definition of glycated hemoglobin (Pagana & Pagana, 1996), the 1997 American Diabetes Association's standards of diabetes medical care, and current recommendations for evaluating diabetes management interventions (Kolaczynski & Goldstein, 1997). Post measure was conducted four months (120 ± 14 days) after completion of each Diabetes Patient Education Program.

The laboratory within this research setting was used to obtain and process the whole blood specimens; no patient preparation was required. Strict controls were maintained in this laboratory setting in conjunction with federal, national, professional, and military regulations. The facility's laboratory met all standards of the Food and Drug Administration (FDA) and the 1988 Clinical Laboratory Improvement Amendments (CLIA) through a Department of Defense (DOD) program known as CLIP (Clinical Laboratory Improvement Program). Also, this laboratory participated in the College of American Pathologists' (CAP) proficiency testing program for glycated hemoglobin and was fully accredited by this agency.

In addition, this lab had successfully completed inspection by the Joint Commission on the Accreditation of Hospital Organizations (JCAHO) and its military counter-part, the Health Services Assessment (HSA).

Control for specimen collection was provided by two department operating instructions (OI): Patient Reception (1995) and Specimen Collection and Processing (1996). Control for specimen processing was provided by department and manufacturer guidelines: the Glycohemoglobin and HbA1c (Abbott IMx) (1994) Operating Instruction and the Abbott IMx package insert (1992).

The Abbott IMx Glycated Hemoglobin Assay is a boronate affinity-binding assay that is based on the principle of ion capture and yields a percent glycated hemoglobin and a derived percent HbA1c. The percent HbA1c was used in this study; the normal reference range was 4.4-6.4%. Further description of the Abbott IMx Glycated Hemoglobin analyzer and this facility's efforts to ensure quality control are offered in Appendix D.

Procedures

Premeasure

A two-hour researcher's meeting was held prior to the first class of each Diabetes Patient Education Program assessed. Procedures went accordingly:

1. Subjects were met in the laboratory area. Consent forms were reviewed, signed, and witnessed.
2. Subjects were accompanied to the laboratory front desk. Computer order entry was assessed (test, provider, associated clinic), and subject information was verified verbally and by comparison with the individual's photo military identification card (patient's full name, family member prefix [FMP], military sponsor's social security number [SSN], date of birth,

day phone number, and sex). Bar-coded labels were then generated from the computer's database.

3. Subjects proceeded to the phlebotomy workstation area. Subjects were asked to verify their name, sponsor's SSN, and birth date by the phlebotomist. Phlebotomy occurred under clean conditions and within the standards of universal precautions. A specimen of at least 2 ml (only 150 microliters was required for analysis) was obtained in an anticoagulated (EDTA) tube that was color-coded (purple top). The patient identification label was affixed immediately to the blood tube; the tube was then placed in a hematology-specific rocker rack. All tubes were moved to the processing area in less than 25 minutes.
4. Specimens were immediately processed or stored at 2-6 degrees centigrade for up to 7 days as per manufacturer instruction; the laboratory processed HbA1cs 2-3 times per week. (see Appendix D for IMx processing and control information).
5. Subjects were taken to the Diabetes Education Office in Internal Medicine Clinic B to complete the premeasure questionnaires. The researcher reviewed the study and threats to validity (study mortality, seasonal trends, cyclic influences, and the Hawthorne). Subjects completed *The Personal Information Data Sheet* (demographics), the *Nonmedication-Taking Diabetes Self-Efficacy Scale* (NMTDSES), and the *Nonmedication-taking Diabetes Self-Care Scale* (NMTDSCS).
6. Subjects proceeded to the first class of their DPEP program.

Intervention

All subjects completed the remaining seven diabetes education classes for their respective DPEP program.

Postmeasure

7. A post measure reminder notecard was sent to the subjects one week prior to questionnaire mailing and HbA1c order entry.
8. The NMTDSES, the NMTDSCS, and an additional Post-Study Questionnaire (Appendix B) were mailed to the subject's homes 14 days prior to the 120-day study endpoint. HbA1cs were also ordered at this time. Subjects were afforded 28 days (from the mailing of the questionnaires) to complete all post measures. Laboratory procedures for the HbA1c analysis went as previously discussed.
9. A follow-phone call was to be made near the end of this 28-day point if postmeasures had not been received/completed; only one of the six subjects required this reminder phone call.

Summary

A one group pre-test post-test design was employed to evaluate the concepts of self-efficacy, self-care, and metabolic control in a sample of persons with Type 2, diet and exercise controlled diabetes attending an outpatient, integrated, multidisciplinary diabetes educational intervention. The goal of this study was to enhance current knowledge of these concepts and their relationships so that those providing diabetes education might more effectively move the diabetes patient towards optimal metabolic control.

IV. ANALYSIS OF THE DATA

The intent of this study was to: (1) gain further insight into persons with Type 2, diet and exercise controlled diabetes, (2) to examine this target group's self-efficacy, self-care, and metabolic control before and after a diabetes educational intervention, and (3) to describe the relationships among this group's self-efficacy, self-care, and metabolic control. Analysis of the data collected to investigate these issues is presented in this chapter.

Statistical analysis was completed using SAS Version 6.12. Descriptive statistics included frequencies (discrete data) and central tendencies (continuous data). Subjective analysis was performed on three items of the demographic questionnaire and the entire Post-Study Questionnaire. Research questions were answered by alternative methods than originally planned: variable relationships were evaluated using Spearman rank-order coefficients, and pre and post variable differences were assessed using Wilcoxon signed rank tests. A Bonferroni adjustment was used to establish the level of significance for each research question. A post hoc power analysis was performed using PASS Version 6.0 since the sample size was nearly predetermined. Lastly, Cronbach's coefficient alpha was attained for the modified self-efficacy and self-care questionnaires.

Demographic Profile of the Sample

The *Personal Information Data Sheet* (Appendix B) was completed by the subjects during the researcher's meeting held prior to the first class of the Diabetes Patient Education Program. In addition to personal demographic information, this 16-item questionnaire extracted both general (11) and diabetes-related (5) characteristics. Accuracy was ensured by cross-verifying self-reported information with the subjects' medical records and hospital computer database. Analysis of demographic and diabetes-related data was performed only on the six subjects who completed the study.

Table 1 describes data gathered from discrete analysis. A majority of the sample (n = 6) was male (83.3%), Caucasian (83.3%), and retired from the military (83.3%). Five of the subjects listed their education level, which varied from high school (40%) to masters-prepared. Four subjects described their annual income: range $15,000-89,000. Diabetes-related data demonstrated that while half of the subjects (50%) asked to attend the Diabetes Patient Education Program, half (50%) had also had previous education (n = 6). Subjective review indicated that five of the subjects were referred from the Primary Care Clinic while one was sent from Internal Medicine.

Of those who had reported previous diabetes education other than dietary-related, two subjects had attended a glucose meter class while the third had previously attended four of the eight diabetes classes. The classes attended by this particular subject included methods of management/acute complications, coping, meter use, and resources/follow-up. Recent attendance of DPEP classes was unanticipated, because the researcher did not consider that patients might enter the diabetes education series at any time. Such recent DPEP

Table 1
Discrete Demographic Data

Characteristic	Frequency	%
Gender (n = 6):		
Male	5	83.3
Female	1	16.7
Ethnic Background (n = 6):		
Afro-American	1	16.7
Caucasian	5	83.3
Military Status (n = 6):		
Retired	5	83.3
Dependent Spouse	1	16.7
Highest Level Of Education Completed (n = 5):		
High School	2	40.0
2 Year College or Technical Training	1	20.0
4 year college or Bachelors Degree	1	20.0
Masters Degree	1	20.0
Average Yearly Income (n = 4):		
$15,000 - 29,999	1	25.0
$30,000 - 44,999	2	50.0
$75,000 - 89,999	1	25.0
Prior diabetes education other than that by a dietitian? (n = 6)		
Yes	3	50.0
No	3	50.0
Known complications (n = 6):		
None	6	100.0
Presence of hemolytic anemia or significant acute blood loss (n = 6):		
None	6	100.0
Reason for attending DPEP (n = 6):		
Asked to attend	3	50.0
Told to attend	3	50.0

class attendance may have elevated pre-measure self-efficacy and self-care scores and possibly lowered the pre-measure HbA1c. Thus, this finding confounds the data and is a limitation of the study.

Although two subjects initially reported the presence of diabetes-related complications, medical record review indicated that these problems were of a primary nature or were related to different disease processes. Thus, no patients were listed as having diabetes-related complications, and no subjects believed that their medical conditions would interfere with their ability to fulfill the requirements of this research. Additionally, none of the subjects indicated, or had recent history of, a hemolytic anemia or acute blood loss.

Table 2 discusses data that was continuous in nature. The sample (n = 6) typified a Type 2 diabetes population: average age of 61 years (SD = 6.4; range 55-71). However, the duration of diabetes for this sample was much lower than expected with subjects diagnosed from as recently as 3 weeks to those who were diagnosed 4 months ago; the average duration of diabetes was 1.8 months (SD = 1.2).

Table 2 also discusses lifestyle variations among the subjects. Five of the subjects reported that they were 45 minutes or less from the hospital; the majority traveled only 20 minutes. Five of the subjects stated that they had a significant other at home with them greater than 50% of the time while four of the subjects indicated that they were involved in activities outside the home anywhere from 3.0-12.0 hours per day (mean = 7.4 hours; SD = 5.1).

Table 2
Continuous Demographic Data

Characteristic	Mean	SD	Median	IQR	Range
Age (years): (n = 6)	61	6.4	59.5	56-65	55-71
Distance from Hospital (minutes): (n = 5)	26	11.9	20	20-30	15-45
Percent of time someone is home with individual: (n = 5)	76	25.0	80	50-100	50-100
Time spent away from home (hours): (n = 4)	7.4	5.1	7.25	3.0-11.5	3.0-12.0
Duration of Diabetes (months): (n = 6)	1.8	1.2	1.5	1.0-2.0	.75-4.0

SD = Standard Deviation; IQR = Interquartile Range

Descriptive Statistics for Self-Efficacy, Self-Care, and Metabolic Control

The Nonmedication-Taking Diabetes Self-Efficacy Scale (NMTDSES) and Nonmedication-Taking Diabetes Self-Care Scale (NMTDSCS) are both 20-item, six-point Likert scale questionnaires; responses range from 1-strongly agree to 6-strongly disagree with an additional not applicable category. Both scales reflect six types of diabetes behaviors (general, diet, exercise, foot care, blood glucose monitoring, and detecting, preventing, or treating high blood glucose values), though only two subscales exist (general and diet). The item-by-item description of the NMTDSES and the NMTDSCS is as follows: six general (items 1, 2, 3, 4, 19, and 20), seven diet (items 5, 6, 7, 8, 9, 10, 11), two foot care (items 14 & 15), two exercise (items 12 & 13), and three monitoring (items 16, 17, and 18).

Total and subscale scores were summed and the mean calculated for both the NMTDSES and the NMTDSCS (interval data); reversed scoring was conducted on positively worded items, which vary between the NMTDSES and the NMTDSCS (see Chapter III). All in all, the higher the score on either the NMTDSES or the NMTDSCS (maximum score = 6.0), the higher the self-efficacy or self-care (total and subscale). Tables 3 and 5 contain the total and subscale central tendencies for the NMTDSES (self-efficacy) and the NMTDSCS (self-care) while Tables 4 and 6 reflect the mean total and subscale pre to post measure differences for these questionnaires.

Self-efficacy results (Table 3) were based on a sample of six at both pre and post measure. Overall, total and subscale mean self-efficacy scores were moderately high ranging from 4.5 ± 1.0 (pre-measure mean diet self-efficacy) to 5.5 ± 0.6 (pre-measure mean general self-efficacy), the maximum score equal to 6.0. Additionally, diet self-efficacy had the lowest scores (pre 4.5 ± 1.0; post $4.8 + 0.9$) while the scores for total self-efficacy (pre 5.0 ± 0.7; post 5.3 ± 0.6) and general self-efficacy (pre 5.5 ± 0.6; post 5.3 ± 1.0) were similar. Of interest is the fact that all premeasures were generally high, ranging from 5.7-6.0.

Table 3
Central Tendencies of Pre and Post Self-Efficacy Scores (Total and Subscale)

Self-Efficacy Scores	M	SD	Med	IQR	Range
Total Self-Efficacy					
Pre-measures (n = 6)	5.0	0.7	5.0	4.4-5.7	4.4-5.7
Post-measure (n = 6)	5.3	0.6	5.5	4.9-5.7	4.3-5.7
Diet Self-Efficacy					
Pre-measures (n = 6)	4.5	1.0	4.5	3.7-5.3	3.3-5.7
Post-measure (n = 6)	4.8	0.9	5.1	3.9-5.4	3.6-5.9
General Self-Efficacy					
Pre-measures (n = 6)	5.5	0.6	5.7	4.8-6.0	4.7-6.0
Post-measure (n = 6)	5.3	1.0	5.7	5.3-5.8	3.3-6.0

SD = Standard Deviation; IQR = Interquartile Range

Table 4 demonstrates the change in total, diet, and general self-efficacy from premeasure to post. Differences were calculated by subtracting the mean pre-measure scores from the mean post-measure scores. Overall, the change in self-efficacy was small (total self-efficacy = 0.2 ± 0.5, diet self-efficacy = 0.3 ± 0.4, and general self-efficacy = -0.2 ± 0.9). Additionally, diet self-efficacy decreased from pre to post measure (-0.2): however, the SD was greatest (0.9) and the range the most varied (-1.5-1.2) for this subscale.

Table 4
Central Tendencies of Self-Efficacy Total Scale and Subscale Differences

Self-Efficacy Differences (n = 6) (Pre to Post Measure)	M	SD	Med	IQR	Range
Total	0.2	0.5	0.1	-0.1-0.3	-0.1-1.1
Diet	0.3	0.4	0.2	0.1-0.4	-0.1-1.1
General	-0.2	0.9	-0.1	-0.7-0.2	-1.5-1.2

SD = Standard Deviation; IQR = Interquartile Range

Self-care results (Table 5) were based on a sample of five for premeasure and six at post measure: one subject answered all self-care pre-measure items as not applicable. Overall, self-care scores demonstrated a greater degree of variation than did self-efficacy scores: scores ranged from 4.3 ± 0.8 (pre-measure general self-care) to 5.7 ± 0.4 (post-measure general self-care). As noted in self-efficacy, no one scale seemed marked by particularly low or high scores. However, all scales demonstrated an improvement from pre to post measure (Table 6). High premeasure scores were also noted for self-care scores; premeasure self-care scores ranged 5.7-6.0.

Table 5
Central Tendencies of Pre and Post Self-Care Scores (Total and Subscale)

Self-Care Scores	M	SD	Med	IQR	Range
Total Self-Care					
Pre-measures (n = 5)	4.6	0.8	4.7	3.9-4.9	3.7-5.8
Post-measure (n = 6)	5.3	0.6	5.3	5.1-5.9	4.4-6.0
Diet Self-Care					
Pre-measures (n = 5)	4.8	0.9	4.8	4.1-5.2	3.8-6.0
Post-measure (n = 6)	5.0	0.8	5.1	4.6-5.7	3.7-5.9
General Self-Care					
Pre-measures (n = 5)	4.3	0.8	4.1	4.0-4.6	3.5-5.7
Post-measure (n = 6)	5.7	0.4	5.8	5.7-6.0	4.8-6.0

SD = Standard Deviation; IQR = Interquartile Range

Table 6 demonstrates the change in total, diet, and general self-care from premeasure to post. Differences were calculated in the same manner as for self-efficacy. All scale means exhibited a positive change, and the changes overall were greater than those noted in self-efficacy (total self-care = 0.6 ± 0.5, diet self-care = 0.4 ± 0.4, and general self-care = 0.8 ± 0.6). However, the significance of these changes must be determined and are during the analysis for research question two. Additionally, all mean self-care values appear more stable than mean self-efficacy values exhibiting smaller SDs and ranges. Generally speaking, the greatest improvement was noted in the general self-care subscale (0.8 ± 0.6).

Table 6
Central Tendencies of Self-Care Total Scale and Subscale Differences

Self-Care Differences (n = 5) (Pre to Post Measure)	M	SD	Med	IQR	Range
Total	0.6	0.5	0.6	0.2-0.7	0.0-1.2
Diet	0.4	0.4	0.4	0.2-0.6	0.0-1.0
General	0.8	0.6	1.0	0.5-1.0	0.0-1.7

SD = Standard Deviation; IQR = Interquartile Range

A hemoglobin A1c is a whole blood specimen that reflects a patient's average blood glucose level over the past 100-120 days (Pagana & Pagana, 1995). The IMx Glycated Hemoglobin analyzer (Abbott, 1992) was used to process pre and post measure HbA1cs; the normal reference range for this analyzer is 4.4-6.4%. Persons with diabetes may exhibit a hemoglobin A1c of 6.4% or less; however, such a status does not indicate that one is free of diabetes but rather that one's diabetes is well-controlled (ADA, 1997b). Additionally, tight metabolic control is defined as a HbA1c of 7% or less, according to the standards of the American Diabetes Association (1997b) and based on the Diabetes Control and Complications Trial (1993).

The hemoglobin A1c is recorded as a percentage and, therefore, provides continuous data. Central tendencies for pre and post hemoglobin A1c measures are presented in Table 7 (n = 6 for both measures). Most notable are the low values computed for premeasure HbA1c: median = 6.55 and mean = 7.4% $\pm$ 1.8. However, review of the range for pre-measure HbA1c demonstrates that not all subjects were well-controlled (5.6-10.4).

Table 7
Central Tendencies of Pre and Post Hemoglobin A1c Measures

Hemoglobin A1c Measures (%)	M	SD	Med	IQR	Range
Pre-measures (n = 6)	7.4	1.8	6.55	6.5-8.6	5.6-10.4
Post-measure (n = 6)	6.0	0.7	6.0	5.8-6.5	5.1-6.7

SD = Standard Deviation; IQR = Interquartile Range

Table 8 demonstrates that the change in the mean HbA1c from pre to post measure; the change is in the desired and anticipated direction. A negative value indicates that overall hemoglobin A1cs decreased (mean = -1.35% + 1.8) significance to be determined. However, the SD is great at 1.8%, indicating that the change

might not be as dramatic as desired. A review of the range of change for HbA1c measure indicates that one or more of the subjects experienced an increase in their HbA1c (high end of range is equal to .02, a positive value).

Table 8
Central Tendencies of Hemoglobin A1c Differences

Hemoglobin A1c Differences (Pre to Post Measure)	M	SD	Med	IQR	Range
	-1.35	1.8	-1.0	-2.1-0.2	-4.4-0.2

SD = Standard Deviation; IQR = Interquartile Range

Review of the each subject's pre and post measure HbA1cs (Table 9), Post-Study Questionnaires (Appendix B), and medical record information (scheduled screening to assess for the occurrence of a hemolytic anemia or acute blood loss during the study interim) helped explain the increase in certain HbA1cs. Findings truly demonstrate the complexity of metabolic control as described by Padgett (1991).

Table 9
Individual Pre and Post Hemoglobin A1c Measures
(re-coded to ensure privacy)

Subject	Pre HbA1c	Post HbA1c
1	5.6	5.8
2	10.4	6.0
3	8.6	6.5
4	6.5	6.7
5	6.5	6.0
6	6.6	5.1

Table 9 demonstrates that while most subjects experienced a decrease in their HbA1cs, subjects 1 and 4 experienced a 0.2% increase. Although this information is statistically insignificant because of the IMx' s $\pm$3% instrument variation, investigation of these subjects' Post-Study Questionnaires and medical

records indicated that both had endured physiological and psychological stressors during the study interim. At the same time, both of these subjects reported that they had made positive changes in diet and exercise behaviors (decreasing carbohydrate, fat, and cholesterol intake while increasing activity/beginning a formalized exercise routine). In contrast, subject 3---who demonstrated the greatest HbA1c reduction (10.4% to 6.0%)---experienced three familial deaths, two familial major surgeries, and a car accident during the study interim. However, during this same period, this subject made similar positive changes in diet and exercise behaviors and lost 25 pounds.

Additional information gathered from the Post-Study Questionnaire and post-measure medical record review gave insight into subject history over the study duration and diabetes-related behavioral change. In general, all Post-Study Questionnaires reflected positive changes to diet and exercise behaviors. No subjects, besides those discussed, described life stressors, losses or traumas. One subject experienced chronic post-menopausal bleeding but did not meet the exclusion criteria for acute blood loss ($\geq$450 mls), nor did medical record review give evidence of reduced blood counts and/or hemoglobin levels or a diagnosis of anemia. Thus, this subject's data was maintained. All subjects had nondiabetes-related medications manipulated or added; none of these medications were known to significantly affect blood glucose levels according to the literature and the hospital's endocrinologist.

Findings for the Research Questions

Level of Significance

Because three individual statistical tests were performed for each research question, the risk for a Type 1 error was increased. A Type 1 error occurs when one assumes that a significant difference exists between data but actually does not; a Bonferroni adjustment is known to minimize this problem (Burns & Grove, 1993).

The Bonferroni correction for this study was made by selecting a .05 level of significance and then dividing this value by the number of statistical tests performed (3). Thus, the level of statistical significance established for both research questions is *.0167*.

Research Question #1

What are the relationships among self-efficacy, self-care, and metabolic control in persons with Type 2, diet and exercise controlled diabetes?

Correlational analysis was conducted to answer this research question: the Spearman rank-order coefficients (nonparametric) was elected over the Pearson Product Moment (parametric) since normal distribution of values could not be assumed in such a small sample (Munro & Page, 1993). Three Spearman rank-order correlational tests were performed using post measure total-scale means and HbA1c values: total self-efficacy and total self-care, total self-care and metabolic control, and total self-efficacy and metabolic control. The results of this analysis are posted in Table 10.

No significant relationships were identified in the three relationships analyzed (Bonferroni adjusted alpha = 0.0167). However, the strongest relationship was found between total self-efficacy and total self-care (0.83, $p = 0.04$). A weak

relationship was identified between total self-care and metabolic control at 0.28 ($p = 0.58$). Lastly, no relationship was depicted between total self-efficacy and metabolic control (0.0, $p = 1.00$).

Table 10
Relationships Among Self-Efficacy, Self-Care, and Metabolic Control

Variables Compared (Post-Measure)	Spearman Rho	p-value
Total Self-Efficacy and Total Self-Care	0.82857	0.0416
Total Self-Care and Metabolic Control (HbA1c)	0.28989	0.5774
Total Self-Efficacy and Metabolic Control (HbA1c)	0.00000	1.0000

Level of Significance = 0.0167

Research Question #2

What is the difference between pre and post measures of self-efficacy, self-care, and metabolic control in a group of persons with Type 2, diet and exercise controlled diabetes undergoing an outpatient, integrated, multidisciplinary educational intervention?

Analysis of the differences was conducted to answer this research question: a nonparametric test, the Wilcoxon signed rank test, was elected over paired *t*-tests (parametric) since normal distribution of the values could not be assumed in such a small sample (Munro & Page, 1993). The Wilcoxon signed rank test indicates that change occurred from pre to post measure and provides the direction and magnitude of that change. Thus, the greater the change, the greater the Wilcoxon signed Rank statistic; a negative sign only denotes the direction of the change.

Three Wilcoxon signed rank tests were conducted to describe any pre to post measure differences that occurred in total self-efficacy, total self-care, and

metabolic control (HbA1c). Table 11 indicates the Wilcoxon signed rank statistic assigned to each variable assessed. No significant pre to post measure differences were found for any of the study variables (Bonferroni adjusted alpha = 0.0167). The Wilcoxon values for total self-care and metabolic control demonstrated the greatest change (both 7.5; $p = 0.0625$ and 0.1563 respectively); the direction of the change was as expected: decreased (-) for the HbA1c and increased for total self-care. Total self-efficacy exhibited positive change (as anticipated), but the change was minimal.

Table 11
The Differences Between Pre and Post Measures of Self-Efficacy, Self-Care, and Metabolic Control

Variable Compared (Pre to Post-Measure)	Wilcoxon Signed Rank Statistic	p-value
Total Self-Efficacy	4.5	0.4375
Total Self-Care	7.5	0.0625
Metabolic Control (HbA1c)	-7.5	0.1563

Level of Significance = 0.0167

Power Analysis

A post-hoc power analysis was performed because the sample was roughly predetermined (Burns & Grove, 1993) and there was no opportunity to replace those who did not fulfill study requirements. Although the researcher attempted to improve the sample size by extending the study to include participants from a third Diabetes Patient Education Program, no targeted subjects from this program chose to participate.

Table 12 depicts the study's power as associated with pre and post measure variable differences. Each variable's power was less than 80%, the power required to produce statistical significance (Burns & Grove, 1993). Pre to post measure

differences would have been statistically recognized if: (1) total self-efficacy would have been evaluated in a sample of 47, (2) total self-care would have been evaluated in a sample of 7, and (3) the HbA1c would have been evaluated in a sample of 18.

Table 12
Power Analysis
The Differences Between Pre and Post Measures of Self-Efficacy, Self-Care, and Metabolic Control

Variable Compared (Pre to Post-Measure)	Level of Power with Current Sample Size	Sample Size Required for 80% Power
Total Self-Efficacy	11%	47
Total Self-Care	63%	7
Hemoglobin A1c	31%	18

Instrument Reliability

Internal consistency of a research instrument is assessed by a Cronbach's alpha coefficient (Burns & Grove, 1993). A Cronbach's alpha was calculated for the total scales and subscales (diet and general) of both the NMTDSES (self-efficacy) and the NMTDSCS (self-care). A Cronbach's alpha of .70 or greater indicates internal consistency and instrument reliability (Burns & Grove, 1993).

Table 13 illustrates the Cronbach's alpha coefficients for the NMTDSES and NMTDSCS (total scale, diet and general subscales). The NMTDSES and NMTDSCS are considered reliable instruments both attaining a Cronbach's alpha of 0.988. Both NMTDSES subscales demonstrated lower alphas (general = 0.940; diet = 0.864) than the NMTDSCS subscales (general = 0.966; diet = 0.908).

Table 13
Internal Consistency
Reliability of the Nonmedication-Taking Diabetes Self-Efficacy Scale (NMTDSES) and the Nonmedication-Taking Diabetes Self-Care Scale (NMTDSCS)

Scale/Subscale	Cronbach's Alpha NMTDSES	Cronbach's Alpha NMTDSCS
General Subscale	0.940	0.966
Diet Subscale	0.864	0.908
Total Scale	0.988	0.988

Summary

Although further insight of persons with Type 2, diet and exercise controlled diabetes was gained; relationships among self-efficacy, self-care, and metabolic control described; and pre to post measure differences between these variables evaluated; none of the findings proved significant secondary to the small sample size. However, reliability of the modified self-efficacy (NMTDSES) and self-care (NMTDSCS) questionnaires was verified. Findings and limitations of this study are discussed further in Chapter V.

V. DISCUSSION

The purposes of this study were: (1) to describe the relationships among self-efficacy, self-care, and metabolic control and (2) to examine the difference between pre and post treatment measures of self-efficacy, self-care, and metabolic control. The target population was persons with Type 2, diet and exercise controlled diabetes; the treatment was an outpatient, integrated, multidisciplinary diabetes educational intervention.

Pre and post measures of self-efficacy, self-care, and metabolic control were assessed prior to and four months post an outpatient, integrated, multidisciplinary educational intervention. A sample of six persons with Type 2, diet and exercise controlled diabetes was attained by convenience from the accessible population of persons referred to this diabetes education program. Demographics were collected at premeasure while a post-study questionnaire obtained specifics on changes in self-care behaviors and assessed for potential extraneous influences. A general statement of reasons for nonparticipation was attained during sample delineation.

Demographic data, self-efficacy and self-care scores (total and subscale), and metabolic measures were analyzed by evaluating frequencies and central tendencies. Research questions were answered through application of the Spearman rank-order correlational test (relationships among variables) and the Wilcoxon signed ranks test (pre to post measure differences between variables). A

Bonferroni adjustment established the level of significance (0.0167) for both research questions. A post hoc power analysis was performed on the differences between the variables, and reliability testing was conducted on the modified self-efficacy (Nonmedication-Taking Diabetes Self-Efficacy Scale) and self-care (Nonmedication-Taking Diabetes Self-Care Scale) questionnaires.

Limitations

Burns and Grove (1993) list four categories of validity that were described by Cook and Campbell in 1979: statistical conclusion validity, construct validity, internal validity, and external validity. Although great effort was taken to minimize the effects of these threats, some were not anticipated or were beyond the control of the researcher. Limitations known to affect this research include: (1) convenience sampling, (2) sample selection, (3) small sample size, (4) low study power, (5) lack of sample heterogeneity, (6) lack of statistical analysis linking demographic data to the variables, (7) correlation causal ambiguity, (8) non-identification of coping as an extraneous variable, (9) interaction of sample selection and treatment, and (10) an interaction of history and treatment. Other limitations that may have influenced this study include: (1) mono-operational bias, (2) mono-methodological bias, (3) subject apprehension, (4) the Hawthorne effect, (5) experimenter expectancies and (6) experimenter mis-measurement, (7) interaction of testing and treatment, and (8) interaction of setting and treatment. Thus, results from this study need to be interpreted with caution and cannot be generalized beyond the setting; the study exits as a pilot effort to assess instrument reliability.

The evaluation of statistical conclusion validity is primarily concerned with how accurately conclusions drawn from analysis reflect the real world (Burns & Grove, 1993). Controls implemented to reduce invalidity included the selection of nonparametric tests (avoids assumption of normal distribution in small samples), incorporation of a Bonferroni adjustment (reduces chance of Type I error), post-hoc power analysis (reduces chance of Type II error), use of reliable instruments, and use of a standardized treatment. However, the ability to generalize this study's findings was inhibited from the start when the researcher chose to use convenience sampling and chose not to identify a comparison group. Additionally, although a small sample was anticipated, the extreme of this smallness was not, and an attempt to enhance sample size by assessing participants of a third Diabetes Patient Education Program (DPEP) failed. Thus, low study power has confined generalization to this setting and this population.

Statistical conclusion validity is also concerned with how heterogeneity of the respondents affects the variables under study (Burns & Grove, 1993). First, sample heterogeneity did not exist; the sample was biased by Caucasian males who were retired from the military and who had had diabetes for only a short duration. Second, the researcher failed to include any statistical tests that would link demographic and diabetes-related data to the study variables.

Statistical analysis linking demographic and diabetes-related data to self-efficacy, self-care, and metabolic control would have described these relationships and allowed for within group comparison. For instance, such an analysis might have explained the influence of varying education levels and permitted comparisons between those who had previous diabetes education and those who did not, those who asked to attend the DPEP and those who were told to attend,

those who had a significant other at home all the time and those who had support only part of the time, and those who spent a significant amount time away from home and those who did not leave their homes often (reflection of depression).

Although variable influence by demographic and diabetes-related data remains unknown, the unexpected finding that three subjects had recently attended one or more DPEP classes is of particular concern (interaction of history and treatment). Two of the three subjects had attended only one of the DPEP classes (meter instruction), but the third had attended four DPEP classes. Thus, premeasure self-efficacy and self-care mean values may have been elevated and premeasure HbA1c mean values depressed to a greater extent than would have been seen had these subjects been excluded. In conclusion, recent attendance of DPEP classes greatly inhibits the results of the pre to post measure analysis.

Internal validity is of particular concern in this study since the variables have been causally associated in previous research; internal validity is concerned with the extent to which the effects detected in a study are a true reflection of reality, rather than being the result of extraneous variables (Burns & Grove, 1993). Many of the threats associated with internal validity (Burns & Grove, 1993) were believed to have been controlled, minimized, or prevented: (1) the Post-Study Questionnaire and Personal Data Information Sheet captured the effects of maturation and history, (2) the four month lapse between measures prevented a test-retest phenomenon, and (3) a questionnaire cover sheet that defined and gave examples of self-efficacy and self-care deterred concept confusion (improved instrumentation). Additionally, statistical regression (low pre-test scores followed by high post-test scores) did not occur, and the effect of mortality was minimal (attrition of one subject) (Burns & Grove, 1993). However, this research enhanced

the ambiguity typically associated with correlational studies that examine causal influence (Burns & Grove, 1993) because only post-measure data was used to analyze relationships among the variables. Additionally, major sample selection problems occurred and contributed to an interaction between sample and treatment (Burns & Grove, 1993).

Problems with sample selection were partially anticipated but had a greater impact on sample size than predicted. Nonparticipant assessment and post-study literature review helped identify an extraneous variable: stage of coping is believed to have contributed greatly to the small size of the sample. First, the researcher specifically targeted persons with diet and exercise controlled diabetes and chose *not to exclude* persons with a diabetes diagnosis of less than six months to enhance sample size (neither of which previous researchers had done). In doing so, the researcher realized that many of these people might be in an early stage of the disease or possibly recently diagnosed; the sample proved this assumption true (mean duration of diabetes = 1.8 ± 1.2 months). In hindsight, a study conducted by Pibernik-Okanovic, Roglic, Prasek and Metelko (1996) demonstrated that only half of their newly diagnosed diabetes sample (n = 71) exhibited positive coping skills in the immediate period post diagnosis.

Second, rationale gathered from nonparticipants indicated that these people were more concerned with DPEP attendance than research participation; only 4 of the 22 nonparticipants contacted (28 nonparticipants total) actually refused to participate. Explanations were associated with the importance of other life activities (work, social issues related to family and friends, church) and reflected seasonal influence (busy with holiday travel, shopping, and festivities); however, many disbelieved that they actually had diabetes. An additional factor reflecting

the state of nonparticipants was that of the 22 nonparticipants offered a one-to-one diabetes education session, only two partook.

Third, an interaction of sample selection (bias) and treatment occurred yielding high premeasure self-efficacy scores. This phenomenon has been experienced by other researchers and has been attributed to the fact that those who partake in diabetes education programs have higher levels of self-efficacy than those who choose not to participate (Glasgow et al., 1992). Explanations for this assumption are derived from Bandura's theory (1977 a & b), where self-efficacy develops out of the need for control in one's life and relates to the confidence one has in his/her abilities to execute actions required to manage prospective life situations. Additionally, research has shown that those with higher levels of self-efficacy often demonstrate higher levels of motivation, greater coping abilities, and internal locus of control (Bandura, 1986). Together, these three factors indicate that participants had accepted their diagnosis and were prepared to take action to control their diabetes, whereas nonparticipants had not moved to this stage of coping.

Construct validity examines the fit between the conceptual definitions and the operational definitions (Burns & Grove, 1993). Although the self-efficacy and self-care instruments were altered, modification only involved the removal of insulin-related items to suit the population. Additionally, the operational definitions for this study were adopted (self-efficacy) and adapted (self-care) from Hurley's work (1990). Thus, since the original instruments underwent intense evaluation to ascertain construct validity and the operational definitions used for this study were nearly the same, construct validity was not a primary concern in this study.

However, construct validity may also be influenced by mono-operational bias, mono-methodological bias, subject apprehension and the Hawthorne effect, and experimenter expectancies and mismeasurement (Burns & Grove, 1993); the exact influence of any of these factors is unknown in this research. Mono-operational bias may have occurred since only one measure for self-efficacy and self-care was used; mono-operational bias has been problematic in other diabetes self-care research (Glasgow et al., 1985; Glasgow, 1991; Kurtz, 1990). Also, the chance that mono-methodological bias occurred is fairly great since self-report was the only method of measure; self-report has been recognized as a limitation in diabetes outcome research (Glasgow & Osteen, 1992) and is considered a limitation in any study (Burns & Grove, 1993).

Subject or researcher influence on construct validity was not appreciated but may have existed. The subjects may have altered their behavior secondary to research participation (Hawthorne effect) or to please the researcher. However, the researcher does not believe that her expectations interfered with study methodology or results.

External validity is concerned with generalization, which has already been inhibited by low study power in this research effort. Threats to external validity are often uncontrollable but must be recognized: (1) interaction of testing and treatment, (2) interaction of selection and treatment, (3) interaction of setting and treatment, and (4) interaction of history and treatment. The influence of pre-testing subjects is unknown; pre-testing may have sensitized the subjects to the concepts of self-efficacy and self-care but could have no direct influence on metabolic control. Additionally, an interaction between setting and treatment was not appreciated since self-efficacy enhancement is not a stated goal of the

Diabetes Patient Education Program; thus, the educators had no reason to prove self-efficacy was enhanced. However, an interaction between selection and treatment did occur, as was discussed in relation to elevated self-efficacy and self-care premeasure scores. Also discussed previously, an interaction between history and treatment most likely occurred (persons who had recently attended DPEP classes) but was not statistically analyzed.

Discussion

Although limitations in this study were multiple, findings still contribute to the knowledge of factors that influence diabetes outcomes. First, descriptive statistics revealed high premeasure self-efficacy and self-care scores accompanied by low HbA1cs. Second, self-efficacy scores for diet were consistently lower than scores for general and total scales. Third, post hoc power analysis demonstrated that with an appropriate sample size, relationships among self-efficacy, self-care, and metabolic control and differences between pre and post measures of these same variables would have proven significant. And lastly, that the Nonmedication-Taking Diabetes Self-Efficacy Scale and the Nonmedication-Taking Diabetes Self-Care Scale are reliable instruments.

The presentation of high premeasure self-efficacy scores has been discussed; high premeasure self-efficacy scores have occurred in similar studies (Glasgow et al., 1992) and have been linked to high levels of motivation under Bandura's theory of self-efficacy (1977 a & b). High premeasure self-care scores and low HbA1c measures were unexpected and are more difficult to explain.

Glycated hemoglobin is a complex factor that's outcome is determined by multiple contributing factors (Padgett, 1991). Perhaps the low premeasure

HbA1cs can be explained by an earlier diagnosis of diabetes (as advocated by the American Diabetes Association [1997c]), in conjunction with the short duration since diabetes diagnosis: subjects' diabetes was identified at an early stage.

Prior diabetes education may have influenced premeasure self-efficacy, self-care, and metabolic control. Data gathered from those subjects who had recently attended a Diabetes Patient Education Program may have elevated mean premeasure self-efficacy and self-care scores and depressed mean HbA1c values. This assumption is derived from meta-analytic reviews and the linear analysis of Brown (1988 & 1990) and Brown and Hedges (1994): diabetes education indirectly influences metabolic control through improved self-care. However, such relationships cannot be established in this study since analysis did not include interactions between diabetes-related demographics and the variables.

Lastly, descriptive statistics showed that diet self-efficacy exhibited a lower mean score than did total or general self-efficacy. Low scores for diet self-efficacy were consistent with previous research (Kingery & Glasgow, 1989; Glasgow 1991). Exercise is also known to exhibit low self-efficacy scores (Kingery & Glasgow, 1989; Glasgow 1991) but was not measured as a separate subscale by the instruments used in this study.

No statistically significant relationships were identified among the variables; however, total self-efficacy was strongly correlated with total self-care, total self-care exhibited a weak correlational relationship to metabolic control, and total self-efficacy was not at all linked to metabolic control. Despite statistical insignificance among self-efficacy, self-care, and metabolic control, the model adapted from C. David Jenkins' "Pathways for Evaluating Integrated Diabetes Management Programs" (1995, p. 61) adequately guided data analysis. Additionally,

the relationships depicted by the adapted model have generally been supported in the research, as is discussed in the following paragraphs.

First, this study demonstrated that a relationship does exist between self-efficacy and self-care. The existence of this relationship supports Bandura's self-efficacy theory and is consistent with a majority of the research (Crabtree, 1987; Glasgow et al., 1989; Kingery & Glasgow, 1989; Hurley & Shea, 1992; McCaul, et al., 1987; Skelly et al., 1995).

Second, this study established a weak link between self-care and metabolic control, which had been recognized by other studies. Padgett (1991) reported that previous investigations of this relationship provided mixed results, and her study reported a weak link between self-care and metabolic control. In contrast, Kingery and Glasgow (1989) noted a fairly strong relationship between self-care and metabolic control.

Third, this study did not demonstrate any relationship between self-efficacy and metabolic control, which is inconsistent with the literature; however, this researcher believes that two of the three studies reviewed had questionable methods of measure. For example, Grossman et al. (1987) identified a strong link between self-efficacy and metabolic control but did not use a HbA1c to reflect metabolic control. Rapley (1990) also confirmed a strong relationship between these variables but did not use a diabetes-specific self-efficacy measure. Lastly, Kavanaugh et al. (1995), who used a HbA1c to reflect metabolic control and a diabetes-specific self-efficacy measure, found a significant relationship between self-efficacy and metabolic control.

No statistically significant differences were found between pre and post variable measures; however, total self-care and metabolic control demonstrated

the greatest change while total self-efficacy changed minimally (notable ceiling effect). The direction of the observed changes were expected and supported by previous research (Glasgow et al., 1992; Rubin et al., 1989 & 1990) while Glasgow et al. (1992) had noted a considerable self-efficacy ceiling effect with a similar population. However, different from the programs studied by Rubin et al and Glasgow et al, the Patient Diabetes Education Program does not specifically incorporate self-efficacy enhancement interventions (coping and problem-solving skills). At the same time, this study did demonstrate that the DPEP enhanced self-efficacy and that with an appropriate sample size ($n \geq 47$ by post hoc power analysis) the results would have proven significant. Yet, because Skelly et al. (1995) demonstrated that one's diabetes self-efficacy level can increase or decrease over time, the DPEP cannot solely be identified as a causative factor.

Lastly, the Nonmedication-Taking Diabetes Self-Efficacy Scale (NMTDSES) and the Nonmedication-Taking Diabetes Self-Care Scale (NMTDSCS) proved to be reliable instruments. Burns and Grove (1993) noted that a Cronbach's alpha of .70 denotes instrument reliability and that use of a reliable instrument promotes study validity. Both the NMTDSES and the NMTDSCS attained Cronbach's alphas of 0.988; subscales for each demonstrated reliability as well (NMTDSES: diet=0.864, general=0.940; NMTDSCS: diet=0.908, general=0.966. Thus, although no significant findings were reported in this study, reliability of these instruments enhances study validity. Additionally, reliability ensures that these instruments may be used in other Type 2 diabetes studies or in a replication study with a larger sample.

Implications

This descriptive research study provides valuable insight into the cognitive processes of persons with Type 2 diabetes. With this knowledge, diabetes educators might better understand the importance of the thoughts that proceed the actions in diabetes self-care. With an understanding of these thoughts, diabetes educators have the opportunity to see beyond the transference of knowledge, see the patient as a whole, and better comprehend the behaviors that they witness.

An awareness that each person with diabetes has varying degrees of self-efficacy toward particular tasks will encourage diabetes educators to that person as an individual who has weaknesses and strengths in diabetes self-care. The Nonmedication-Taking Diabetes Self-Efficacy Scale and the Nonmedication-Taking Diabetes Self-Care Scale have proved reliable and may be used to discern those areas that need enhancement and those areas that can be built upon.

An understanding of self-efficacy, its importance, and its influence in diabetes self-care might alter the manner in which nurses and other healthcare professionals instruct their diabetes patients. Enhanced knowledge of self-efficacy can be applied in the most formalized, integrated, multidisciplinary diabetes educational efforts or in the most casual one-to-one setting. Program development, revision, and enhancement are often duties charged to the diabetes educator; knowledge of self-efficacy could precipitate a diabetes education program of the highest quality yielding the greatest benefit.

Nurses who incorporate the self-efficacy concept in diabetes instruction not only have the opportunity to affect the patient's self-efficacy but to affect the understanding that other healthcare professionals have of this concept. Whether

organized into an integrated team or functioning as an individual component, patients with diabetes will have contact with physicians, dieticians, exercise specialists, pharmacists, ophthalmologists, podiatrists, etc. Many of these professionals function from a medical model and lose sight of individuality and wholeness; all they know is that they want the patient to do what they tell them to do. Nurses have the responsibility to enlighten these professionals about the concept of self-efficacy, particularly self-efficacy's connection to self-care. By doing so, diabetes patients will have the opportunity to reap self-efficacy enhancement benefits from all facets of diabetes management.

Lastly, if nurses are unable to change the practice of others, they have the responsibility to protect the patients' rights and bridge the gap between medical management and personal care. Demeaning lectures of the need to attain tight metabolic control often create patient frustration, enhance feelings of hopelessness, and deplete personal self-efficacy. Again, the nurse has the responsibility to ensure the patient understands this drive for tight metabolic control, has the appropriate skills and knowledge to perform the behaviors that might move the patient toward tight metabolic control, and has the confidence in himself or herself to achieve improved metabolic control.

Recommendations for Future Research

This study has several implications for future research. Altering research design and the sampling procedure and repeating this study in the same setting could produce statistically significant results. For instance, an adequate sample size could be achieved by extending the study over a year's time, gathering subjects from 12 Diabetes Patient Education Programs. The quality of the sample

could be enhanced by the addition of exclusion criteria that alleviate identified extraneous variables (increased homogeneity) (Burns & Grove, 1993): for example, research participation would be prohibited if the subject has attended any DPEP classes in the past year or if the subject has a diabetes diagnosis of less than six months.

Validity and generalization of a replication study could be enhanced by various means. First, random sampling and a control group could be incorporated, or at least a non-treated comparison group identified (Burns & Grove, 1993); the addition of a control group would also verify the occurrence of an interaction between selected subjects and the treatment. If, however, the researcher was unable to obtain a control or comparison group, quota sampling would at least ensure appropriate representation of minority groups in convenience sampling (women, African-Americans, non-retired-military persons) (Burns & Grove, 1993). Second, conducting this study in other diabetes education programs locally and abroad would provide additional information about self-efficacy enhancement and Type 2 diet and exercise controlled diabetes populations, strengthening further the validity, the findings, and the ability to generalize.

However, if replication is performed, data analysis should be adjusted. Incorporating an evaluation of the relationships between general demographic and diabetes-related information and the variables of self-efficacy, self-care, and metabolic control would more readily prepare the researcher to explain outlier variable values or identify extraneous variables that need to be controlled in an ensuing study. Additionally, the use of statistical tests, which more formally imply causation (regression), would alleviate the causal ambiguity associated with correlational analysis (Burns & Grove, 1993). Lastly, subscale analysis (differences,

relationships, predictive qualities) would provide the researcher with greater information about diet and general self-efficacy and self-care as observed in other research (Glasgow et al., 1989; McCaul et al., 1987).

Study design could be further altered to perform repeated measures over time, as has been done by other researchers (Kavanaugh et al., 1993; Glasgow et al., 1989; Kingery & Glasgow, 1989; McCaul et al., 1987; Skelly et al., 1995). Such an application of the NMTDSES and the NMTDSCS would provide insight to the stability of self-efficacy over time since some who have conducted similar research have witnessed an instability of this variable over the duration (Skelly et al., 1995). Additionally, repeated measures of self-efficacy, self-care, and metabolic control over time would provide multiple sets of data to analyze intervariable relationships, strengthening the validity of the findings.

Expanding the study to include pre and post measures of knowledge and coping would help explain the effects of these confounding variables. Analysis of the co-variance could then be performed measuring the influence of these extraneous variables. An even greater appreciation of coping could be obtained in those with newly diagnosed diabetes or those who chose not to participate in diabetes education through qualitative review.

Altering instrumentation by changing the instruments or the methods of measure could improve the efficacy of self-efficacy and/or self-care studies. Mono-operational and mono-methodological bias could be reduced by incorporating multiple methods of measure for self-care (Glasgow et al., 1985) and possibly adding home glucose monitoring results for metabolic measure; however, self-efficacy has only ever been measured by self-report.

Lastly, adding a formal exercise subscale could enhance the efficacy of the NMTDSES and the NMTDSCS in populations not taking medications to control their diabetes. Exercise is an essential element of diabetes management and exhibits similar self-efficacy and self-care characteristics to that of diet: exercise is one of the most difficult self-care behaviors to incorporate, typically demonstrates low self-efficacy scores, and generally demonstrates a fairly strong predictive relationship between its self-efficacy and its self-care behavior (Glasgow, 1991; McCaul et al., 1987).

Appendix A

Original Instruments

The following statements describe what some people believe about their ability to take care of their diabetes. Please take the next few minutes to tell me what you believe about your ability to manage your diabetes. After reading each statement, circle the number that best expresses your beliefs. There are twenty eight (28) statements, please answer each one. There are no right or wrong answers.

Circle 1 if you strongly agree with the statement,
2 if you moderately agree with the statement,
3 if you slightly agree with the statement,
4 if you slightly disagree with the statement,
5 if you moderately disagree with the statement,
6 if you strongly disagree with the statement,
or NA if the statement does not apply to you.

EXAMPLE. I can test my urine for sugar before meals when I am away from home. 1 2 3 4 5 6 NA

ANSWER. If you are confident in your ability to test your urine before meals when you eat out, you should circle 1 because that statement best expresses your belief. If you do not test urine, you should circle NA.

1. I can carry out practically all of the self care activities in my daily diabetes routine.	1	2	3	4	5	6	NA
2. I am confident in my ability to manage my diabetes.	1	2	3	4	5	6	NA
3. I feel unsure about having to use what I know about diabetes self treatment every day.	1	2	3	4	5	6	NA
4. I don't think I can follow my diabetes routines every single day.	1	2	3	4	5	6	NA
5. I can eat my meals at the same time every day.	1	2	3	4	5	6	NA
6. I can stay on my diabetic diet when I eat in familiar places away from home (such as at a friend's house).	1	2	3	4	5	6	NA
7. I can stay on my diabetic diet when I eat in unfamiliar places.	1	2	3	4	5	6	NA
8. I'm not sure I'll be able to stay on my diabetic diet when the people around me don't know that I have diabetes.	1	2	3	4	5	6	NA
9. I'm not sure I'll be able to follow my diabetic diet every day.	1	2	3	4	5	6	NA
10. I can correctly exchange one food for another in the same food group.	1	2	3	4	5	6	NA

11. When I go to parties, I can follow my diet plan.	1	2	3	4	5	6	NA
12. I can exercise several times a week.	1	2	3	4	5	6	NA
13. I can't exercise unless I feel like exercising.	1	2	3	4	5	6	NA
14. I can figure out when to call my doctor about problems with my feet.	1	2	3	4	5	6	NA
15. I can routinely apply the recommended lotion to my feet.	1	2	3	4	5	6	NA
16. I cannot test my blood or urine when I am away from home.	1	2	3	4	5	6	NA
17. I can recognize when my blood sugar is too high.	1	2	3	4	5	6	NA
18. When I feel sick I can test my blood or urine more than I routinely do.	1	2	3	4	5	6	NA
19. I can take my insulin using the recommended procedure.	1	2	3	4	5	6	NA
20. I may have difficulty taking my insulin when away from home.	1	2	3	4	5	6	NA
21. I can adjust my insulin dose based on the results of my urine or blood tests.	1	2	3	4	5	6	NA

22. I'm not sure I can figure out what to do about my insulin dose when changes occur in my usual routine.	1	2	3	4	5	6	NA
23. I can do what was recommended to prevent low blood sugar reactions When I exercise.	1	2	3	4	5	6	NA
24. I can figure out what self treatment to administer when my blood sugar gets higher than it should be.	1	2	3	4	5	6	NA
25. I'm not sure I can recognize when my blood sugar is low.	1	2	3	4	5	6	NA
26. I'm not sure I can adjust my diabetes self treatments if I get a cold or the flu.	1	2	3	4	5	6	NA
27. I can fit my diabetes self treatment routine into my usual life style.	1	2	3	4	5	6	NA
28. I think I'll be able to follow my diabetes plan even when my daily routine changes.	1	2	3	4	5	6	NA

Do you have any comments you wish to add about confidence in your ability to self manage diabetes?

-THANK YOU-

The following statements describe what some people do to take care of their diabetes. Please take the next few minutes to tell me what you have been doing to manage your diabetes. After reading each statement, circle the number that best expresses your beliefs. There are twenty eight (28) statements, please answer each one. There are no right or wrong answers.

Circle 1 if you strongly agree with the statement,
2 if you moderately agree with the statement,
3 if you slightly agree with the statement,
4 if you slightly disagree with the statement,
5 if you moderately disagree with the statement,
6 if you strongly disagree with the statement, or
NA if the statement does not apply to you.

EXAMPLE. I tested my urine for sugar before meals when I was away from home. 1 2 3 4 5 6 NA

ANSWER. If you almost always tested your urine before meals when you ate out, you should circle 1 because that statement best expresses how you managed your diabetes. If you never tested when you ate out, you should circle 6. If you do not test urine, you should circle NA.

1. I carried out practically all of the activities in my daily self care diabetes routine.	1	2	3	4	5	6	NA
2. I managed my diabetes very well.	1	2	3	4	5	6	NA
3. I was able to use what I know about my diabetes self treatment every day.	1	2	3	4	5	6	NA
4. I followed my diabetes self care routines every single day.	1	2	3	4	5	6	NA
5. I ate my meals at the same time every day.	1	2	3	4	5	6	NA
6. I stayed on my diabetic diet when I ate in familiar places away from home (such as at a friend's house).	1	2	3	4	5	6	NA
7. I stayed on my diabetic diet when I ate in unfamiliar places.	1	2	3	4	5	6	NA
8. I stayed on my diabetic diet when the people around me did not know that I have diabetes.	1	2	3	4	5	6	NA
9. I followed my diabetic diet every day.	1	2	3	4	5	6	NA
10. I correctly exchanged one food for another in the same food group.	1	2	3	4	5	6	NA

11. When I went to parties, I followed my diet plan.	1	2	3	4	5	6	NA
12. I exercised several times a week.	1	2	3	4	5	6	NA
13. I exercised even when I did not feel like exercising.	1	2	3	4	5	6	NA
14. I figured out when to call my doctor about problems with my feet.	1	2	3	4	5	6	NA
15. I routinely applied the recommended lotion to my feet.	1	2	3	4	5	6	NA
16. I tested my blood or urine when I was away from home.	1	2	3	4	5	6	NA
17. I recognized when my blood sugar was too high.	1	2	3	4	5	6	NA
18. When I felt sick I tested my blood or urine more often than I routinely do.	1	2	3	4	5	6	NA
19. I self administered my insulin using the recommended procedure.	1	2	3	4	5	6	NA
20. I took my insulin when away from home.	1	2	3	4	5	6	NA
21. I adjusted my insulin dose based on the results of my urine or blood tests.	1	2	3	4	5	6	NA

22. I figured out what to do about my insulin dose when changes occurred in my usual routine.	1	2	3	4	5	6	NA
23. I did what was recommended to prevent low blood sugar reactions when I exercised.	1	2	3	4	5	6	NA
24. I figured out what self treatment to administer when my blood sugar was higher than it should be.	1	2	3	4	5	6	NA
25. I recognized when my blood sugar was low.	1	2	3	4	5	6	NA
26. I adjusted my diabetes self treatments when I got a cold or the flu.	1	2	3	4	5	6	NA
27. I fit my diabetes self treatment routine into my usual life style.	1	2	3	4	5	6	NA
28. I followed my diabetes plan even when my daily routine changed.	1	2	3	4	5	6	NA

Do you have any comments you wish to add about self managing diabetes?

Appendix B

Instruments for Data Collection

SELF-EFFICACY, SELF-CARE, AND METABOLIC CONTROL IN DIABETES

a research study conducted by
Major Lisa M. A. Randall, USAF, NC
in partial fulfillment of the requirements for the degree of
Master of Science
Wright State University, Dayton, Ohio

Part I
The Nonmedication-Taking
Self-Efficacy Questionnaire

Thank you for your participation in this research effort. This is *Part I* of two questionnaires you will be asked to complete. The two questionnaires may appear very similar, but actually measure two different aspects of your diabetes self-care.

Please observe the definitions and examples provided on each questionnaire. This guidance should help you distinguish the difference between the two questionnaires.

Please answer all of the twenty (20) statements that follow. There are no right or wrong answers. Circle the number that best estimates your belief about the statement. Choices include:

1 strongly agree with the statement
2 moderately agree with the statement
3 slightly agree with the statement
4 slightly disagree with the statement
5 moderately disagree with the statement
6 strongly disagree with the statement
N/A if the statement does not apply to you

Self-efficacy reflects what you *believe* about your ability to manage your diabetes. Read each statement then circle the number that best estimates how you feel.

Example: I think I can follow my diabetes routines every single day. 1 2 3 4 5 6 N/A

1	strongly agree with the statement
2	moderately agree with the statement
3	slightly agree with the statement
4	slightly disagree with the statement
5	moderately disagree with the statement
6	strongly disagree with the statement
N/A	if the statement does not apply to you

Do not write in this block
SUBJECT ID #

_____

1. I can carry out practically all of the self-care activities in my daily diabetes routine.	1	2	3	4	5	6	N/A
2. I am confident in my ability to manage my diabetes.	1	2	3	4	5	6	N/A
3. I feel unsure about having to use what I know about diabetes self treatment (care) every day.	1	2	3	4	5	6	N/A
4. I don't think I can follow my diabetes routines every single day.	1	2	3	4	5	6	N/A
5. I can eat my meals at the same time every day.	1	2	3	4	5	6	N/A
6. I can stay on my diabetic diet when I eat in familiar places away from home (such as at a friend's house).	1	2	3	4	5	6	N/A
7. I can stay on my diabetic diet when I eat in unfamiliar places.	1	2	3	4	5	6	N/A

1	strongly agree with the statement
2	moderately agree with the statement
3	slightly agree with the statement
4	slightly disagree with the statement
5	moderately disagree with the statement
6	strongly disagree with the statement
N/A	if the statement does not apply to you

Do not write in this block
SUBJECT ID #

_____

8. I'm not sure I'll be able to stay on my diabetic diet when the people around me don't know I have diabetes.	1	2	3	4	5	6	N/A
9. I'm not sure I'll be able to follow my diabetic diet every day.	1	2	3	4	5	6	N/A
10. I can correctly exchange one food group for another in the same food group.	1	2	3	4	5	6	N/A
11. When I go to parties, I can follow my diet plan.	1	2	3	4	5	6	N/A
12. I can exercise several times a week.	1	2	3	4	5	6	N/A
13. I can't exercise unless I feel like exercising.	1	2	3	4	5	6	N/A
14. I can figure out when to call my doctor about problems with my feet.	1	2	3	4	5	6	N/A

1	strongly agree with the statement
2	moderately agree with the statement
3	slightly agree with the statement
4	slightly disagree with the statement
5	moderately disagree with the statement
6	strongly disagree with the statement
N/A	if the statement does not apply to you

Do not write in this block
SUBJECT ID #
_____

15. I can routinely apply the recommended lotion to my feet.	1	2	3	4	5	6	N/A
16. I cannot test my blood or urine when I am away from home.	1	2	3	4	5	6	N/A
17. I can recognize when my blood sugar is high.	1	2	3	4	5	6	N/A
18. When I feel sick I can test my blood or urine more than I routinely do.	1	2	3	4	5	6	N/A
19. I can fit my diabetes self treatment (care) routine into my usual lifestyle.	1	2	3	4	5	6	N/A
20. I think I'll be able to follow my diabetes plan even when my daily routine changes.	1	2	3	4	5	6	N/A

Thank you for your participation!

SELF-EFFICACY, SELF-CARE, AND METABOLIC CONTROL IN DIABETES

a research study conducted by

Major Lisa M. A. Randall, USAF, NC

in partial fulfillment of the requirements for the degree of
Master of Science
Wright State University, Dayton, Ohio

Part II

The Nonmedication-Taking

Self-Care Questionnaire

Thank you for your participation in this research effort. This is *Part II* of two questionnaires you will be asked to complete. The two questionnaires may appear very similar, but actually measure two different aspects of your diabetes self-care.

Please observe the definitions and examples provided on each questionnaire. This guidance should help you distinguish the difference between the two questionnaires.

Please answer all of the twenty (20) statements that follow. There are no right or wrong answers. Circle the number that best estimates your belief about the statement. Choices include:

1 strongly agree with the statement
2 moderately agree with the statement
3 slightly agree with the statement
4 slightly disagree with the statement
5 moderately disagree with the statement
6 strongly disagree with the statement
N/A if the statement does not apply to you

Self-care reflects what you *have been doing* to manage your diabetes. Read each statement then circle the number that best estimates what you do.

Example: I did follow my diabetes routines every single day. 1 2 3 4 5 6 N/A

1	strongly agree with the statement
2	moderately agree with the statement
3	slightly agree with the statement
4	slightly disagree with the statement
5	moderately disagree with the statement
6	strongly disagree with the statement
N/A	if the statement does not apply to you

Do not write in this block
SUBJECT ID #

_____

1. I carried out practically all of the activities in my daily self-care diabetes routine.	1	2	3	4	5	6	N/A
2. I managed my diabetes very well.	1	2	3	4	5	6	N/A
3. I applied my knowledge to my diabetes self treatments (care) every day.	1	2	3	4	5	6	N/A
4. I did not follow my diabetes self-care routines every single day.	1	2	3	4	5	6	N/A
5. I ate my meals at the same time every day.	1	2	3	4	5	6	N/A
6. I stayed on my diabetic diet when I ate in familiar places away from home (such as at a friend's house).	1	2	3	4	5	6	N/A
7. I did not stay on my diabetic diet when I ate in unfamiliar places.	1	2	3	4	5	6	N/A

1	strongly agree with the statement
2	moderately agree with the statement
3	slightly agree with the statement
4	slightly disagree with the statement
5	moderately disagree with the statement
6	strongly disagree with the statement
N/A	if the statement does not apply to you

Do not write in this block
SUBJECT ID #

8. I stayed on my diabetic diet when the people around me did not know that I have diabetes.	1	2	3	4	5	6	N/A
9. I did not follow my diabetic diet every day.	1	2	3	4	5	6	N/A
10. I correctly exchanged one food group for another in the same food group.	1	2	3	4	5	6	N/A
11. When I went to parties, I did not follow my diet plan.	1	2	3	4	5	6	N/A
12. I exercised several times a week.	1	2	3	4	5	6	N/A
13. I did not exercise when I did not feel like exercising.	1	2	3	4	5	6	N/A
14. I did not figure out when to call my doctor about problems with my feet.	1	2	3	4	5	6	N/A

1	strongly agree with the statement
2	moderately agree with the statement
3	slightly agree with the statement
4	slightly disagree with the statement
5	moderately disagree with the statement
6	strongly disagree with the statement
N/A	if the statement does not apply to you

Do not write in this block
SUBJECT ID #

_____

15. I routinely applied the recommended lotion to my feet.	1	2	3	4	5	6	N/A
16. I tested my blood or urine when I was away from home.	1	2	3	4	5	6	N/A
17. I recognized when my blood sugar was too high.	1	2	3	4	5	6	N/A
18. When I felt sick I did not test my blood or urine more than I routinely do.	1	2	3	4	5	6	N/A
19. I fit my diabetes self treatment (care) routine into my usual lifestyle.	1	2	3	4	5	6	N/A
20. I did not follow my diabetes plan even when my daily routine changed.	1	2	3	4	5	6	N/A

Thank you for your participation!

SELF-EFFICACY, SELF-CARE, AND METABOLIC CONTROL IN DIABETES

a research study conducted by

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Post-Study Questionnaire

Because this research study has extended over a five (5) month period, various events could have occurred that might affect your final self-efficacy or self-care answers, or hemoglobin A1c results. The purpose of this additional questionnaire is to help identify any such factors. Please complete the following questions.

1. Have you experienced any ***life traumas or stressors*** (deaths in the family, traumatic accidents, other serious medical problems, unexpected financial hardships, etc.) since the first day of the Patient Diabetes Education Class? Yes ☐ No ☐

   If YES, please briefly describe these events and how you were affected by them:_____

   _____

   _____

   _____

2. Because the hemoglobin A1c may be affected by certain medical conditions:

   Have you been diagnosed with a ***hemolytic anemia*** (a condition where the red blood cells are destroyed) since the start of this study?

   Yes ☐ No ☐ Not sure ☐

   Have you experienced any ***significant blood loss within the last 30 days*** (Approximately one unit or 2 cups or 16 oz. Most likely this would result from a major surgery or traumatic accident.)?

   Yes ☐ No ☐ Not sure ☐

Do not write in this block	SUBJECT ID # _____

Were you started on ***any new medications*** since the first day of the Patient Diabetes Education Program? List all and why you were placed on them, even if only for a short period of time (i.e., antibiotic X for 10 days because of a urinary tract infection).

MEDICATION	**REASON**
_____	_____
_____	_____
_____	_____

4. Have you been ***ill or experienced any infections*** since the first day of the Patient Diabetes Education Class? Yes ☐ No ☐

   If YES, please briefly describe:_____

_____

_____

_____

5. Describe how your ***activity level*** has changed since the first Diabetes Patient Education class._____

_____

_____

_____

_____

6. Describe how your ***diet*** has changed since the first Diabetes Patient Education class._____

_____

_____

_____

_____

Do not write in this block SUBJECT ID # _____

Do not write in this block SUBJECT ID #
_____

Personal Information Data Sheet

Please complete the following items as best as you are able. Some of the requested information may seem personal, but will help describe the type of patients that are typically referred to the diabetes education program. Confidentiality will be maintained by assigning a number to represent the information you provide. A master list will be created, and kept locked in a firesafe box to which only I have a key.

If you are unable to provide some of the information or unsure of its accuracy, I should be able to complete this information by accessing your medical records and/or hospital computer data base. Privacy will be maintained according to the Privacy Act of 1974. The information you provide will only be used for the purposes of this research.

Full Name:_____ FMP/SSN: ____/_____

Address:_____

_____

_____

Telephone: (___)_____

Back-Up Contact Number: (___)_____

Thank you for your participation. If you would like a copy of the research findings when they become available, please check this box.

☐

LISA M. A. RANDALL, Maj, USAF, NC
(937) 431-0139

Do not write in this block SUBJECT ID #
_____

A. Age:_____

Birthdate:_____(D/M/Y)

B. Gender:

(1) Male

(2) Female

C. Ethnic background:

(1) Afro-American

(2) Hispanic

(3) Asian

(4) Caucasian

(5) Pacific Islander

(6) Other

D. Military status:

(1) Active Duty

(2) Retired

(3) Dependent Spouse

(4) Dependent Child

(5) Other

E. Highest level of education completed:

(1) Less than high school

(2) High school

(3) 2 year college or technical training

(4) 4 year college or bachelors degree

(5) Masters degree

(6) Post-graduate

F. Average yearly income:

(1) Less than $15,000	(5) 60,000 - 74,999
(2) $15,000 - 29,999	(6) 75,000 - 89,999
(3) $30,000 - 44,999	(7) $90,000 or more
(4) 45,000 - 59,999	

Do not write in this block
SUBJECT ID #
_____

G. How far away do you live from this hospital?

Hours:_____ Minutes:_____

H. What percent of the time is someone at home with you?

_____%

I. On the average, how many hours do you spend away from home per day? (working, running errands, doing leisure activities, volunteering, etc.)

Hours:_____ Minutes:_____

J. How long have you had diabetes?

Years:_____ Months:_____

K. Have you had prior diabetes education before, other than that given by a dietitian?

(1) Yes

(2) No

If Yes, describe that education:_____

_____

L. What complications of diabetes are you aware that you have? (circle as many as are appropriate)

(1) Problems with your eyes

(2) Problems with your kidneys

(3) Problems with your heart

(4) Problems with your circulation

(5) Problems with the nerves in your feet and/or hands

Do not write in this block SUBJECT ID #
_____

M. Do you believe that any of these complications would prevent you from completing this research study?

(1) Yes

(2) No

If yes, list which ones using numbers from item M. above:_____

_____

N. The hemoglobin A1c may be affected by certain medical conditions. Two conditions are of particular concern. Please check those that pertain to you:

Hemolytic Anemia (a condition where red blood cells are destroyed) ☐

Any Significant Blood Loss Within The Last 30 Days (Approximately one unit or 2 cups or 16 oz. Most likely this would result from a major surgery or traumatic accident) ☐

I do not think I have either of these problems. ☐

O. What clinic and which provider referred you to the Diabetes Patient Education Program?

Clinic:_____Provider:_____

P. Select the number which best applies to your situation:

(1) I *asked* to attend a diabetes education program.

(2) I *was told* to attend a diabetes education program.

Thanks Again!

Appendix C

The Patient Diabetes Education Program

Patient Diabetes Education Program

The Patient Diabetes Education Program is a monthly program that consists of eight group-type sessions taught by a multidisciplinary staff. Patients are encouraged to bring a significant other, and to complete all sessions despite previous education. Patients are afforded the opportunity to make-up missed sessions in the following month's program. Referred patients will be invited to attend programs twice. If no response is received, the consultation sheet is returned to the primary provider.

The following is a brief summary of the individual Patient Diabetes Education Program sessions. This list includes the subjects to be taught, instructing discipline, length of the session and written teaching objectives. The diet instruction and blood sugar monitoring classes are held twice a month, and patients may select the one that bests fits their schedule. The order of the classes is dependent upon when the participant chooses to take their blood sugar monitoring and diet instruction sessions, and may be altered by the administrating CDE to meet with the schedule demands of the instructors.

SESSION	INSTRUCTOR	LENGTH
Class 1: **Introduction to Diabetes**	CDE	2 hours

By the end of this session, the participant will be able to identify:

1. The definition of diabetes.
2. His/her own type of diabetes.
3. Three symptoms of diabetes.
4. Desired blood sugar values.
5. Two Characteristics of Type I diabetes.
6. Two Characteristics of Type II diabetes.
7. How to calculate his/her ideal body weight.
8. Four goals in managing diabetes.
9. Five treatment tools for the control of diabetes.

**Note:* A HbA1c will be ordered for the patient if not available.

Class 2:

Acute Complications/Emergencies	CDE	2 hours
Methods of Management	CDE	
Exercise and Diabetes	Physical Therapy	

By the end of this session, the participant will be able to identify, state or describe:

1. Define low blood sugar.
2. Recognize three signs of low blood sugar.
3. Describe the appropriate way to treat low blood sugar.
4. Define ways to prevent low blood sugar.
5. Define high blood sugar.
6. Recognize the signs of high blood sugar.
7. Describe the appropriate measures to take should high blood sugar occur.
8. Define ways to prevent high blood sugar.
9. Describe sick day recommendations.
10. Weight loss and physical activity are the best methods of managing Type II diabetes.
11. Consistent diet, insulin, and activity are the best methods of managing Type I diabetes.
12. How oral agents work.
13. State oral agents are not insulin.
14. When to take his/her oral agent.
15. Drugs that may interact with oral agents.
16. Common side effects of oral agents.
17. Oral agents that work best when combined with diet and exercise.
18. State alcohol may interact with some oral agents.
19. Define insulin, where it comes from, and what it does.
20. State that different kinds of insulin vary in source, strength, and length of action.

Class 3:

Coping with Diabetes	Mental Health	2 hours

By the end of this session, participants will be able to:

1. Identify normal emotional responses to the diagnosis of diabetes.
2. Normalize emotional responses to the diagnosis of diabetes.
3. Identify behavioral steps required for adjusting to diabetes.
4. Identify resources available for supporting the behavioral steps required for adjusting to diabetes.

Class 4:

Hypertension and Diabetes	Endocrinology	1.5 hours
Heredity and Diabetes	Endocrinology	
Rationale for Close Control	Endocrinology	

By the end of this session, participants will be able to:

1. State in basic terms the impact of hypertension on the bodily organs of a person with diabetes.
2. Discuss in basic terms the relationship of heredity to the participant's type of diabetes, and how others within their family might be affected.
3. Discuss in basic terms how close glycemic control may prevent or delay many of the chronic complications of diabetes (Results and Implications of the Diabetes Control and Complication Trials [1993]).

Class 5:

Chronic Complications	CDE	2 hours
Foot Care for People with Diabetes	Podiatrist/CDE	

By the end of this session, participants will be able to:

1. Identify the most common chronic complications of diabetes.
2. State that good blood sugar control can decrease complications by 60-75%.
3. Identify those physiological changes that put the person with diabetes at risk for foot problems.
4. Identify four good foot care strategies.
5. Identify four ways to prevent injury to the feet.

Class 6:

Resources for People with Diabetes	CDE	2 hours
Importance of Follow-Up	Endocrinology	
Travel and Diabetes	CDE	

By the end of this session, participants will be able to identify:

1. Two local organizations that help people with diabetes.
2. Two publications for people with diabetes.
3. Three assessments that should be made at each follow-up visit.
4. Two travel considerations for people with diabetes.

Class 7:

Blood Sugar Testing Class	CDE	2 hours
How to Use a Blood Sugar Meter	CDE	

By the end of this session, participants will be able to:

1. Identify the desired blood glucose range.
2. Identify a personal testing schedule.
3. Demonstrate a visual test (per vendor guide).
4. Demonstrate the use of a blood glucose meter (per vendor guide).
5. State that they will notify the M.D. for a persistent blood glucose above 240 mg/dl or below 60 mg/dl.
6. Demonstrate record keeping procedures.
7. State that they will monitor more frequently during illness and stress.
8. State that urine testing is less informative than blood glucose testing.

Class 8:

Diet Instruction	Dietary	1.5 hours
Meal Planning	Dietary	

By the end of this session, participants will be able to:

1. Identify three goals of the ADA Diet Plan for people who have diabetes.
2. Explain the relationship of food intake to blood glucose level.
3. Explain the six primary nutrients found in food.

4. State the names of the three nutrients which affect blood glucose level.

5. Recognize the relationship of a nutritionally adequate diet to body health.

6. Compare the effect of carbohydrate, protein, and fat absorption on blood glucose.

7. Define carbohydrate.

8. List four food groups which contain carbohydrates.

9. Differentiate between simple and complex carbohydrate food sources.

10. Compare the effect of simple and complex carbohydrate absorption on blood glucose.

11. Define the concept of food exchange groups.

12. Explain why the kind and number of exchanges planned may differ from person to person.

13. Name the six food exchange groups.

14. Find each exchange list in AFP-166-23 booklet (Dietary Information for the Person with Diabetes).

15. Use each exchange list to locate given food serving portions.

16. Identify which exchange groups contain carbohydrate.

17. Differentiate between foods which contain primarily simple carbohydrates and those which contain complex carbohydrates.

18. Identify the exchange groups that should remain at the meal planned.

19. Identify the exchange groups that can be moved to another meal.

20. Explain the reason for consistency in amount, composition and time of food intake from day to day.

21. Differentiate between food sources of polyunsaturated and saturated fat. Explain how to reduce the fat intake in your diet.

22. State the effect of increased dietary fiber on blood glucose level and the health benefits of fiber.

23. Identify two benefits of weight reduction for the overweight diabetic person.

24. State his/her ideal body weight.

25. Explain how to read labels and identify low fat foods, high sugar foods, and misleading labels.

26. Identify the benefits of exercise for the diabetic person.

27. Identify four blood lipids and how to improve their levels with diet and exercise.

28. Explain the long-range complications of diabetes.

Appendix D

The IMx Glycated Hemoglobin

The Abbott IMx Glycated Hemoglobin (1992) is an ion capture assay that uses boronate affinity binding to quantify the percent glycated hemoglobin in human anticoagulated whole blood. The percent HbA1c is derived from the percent total glycated hemoglobin using a linear equation that was defined during an extensive correlational study with an ion-exchange high-performance liquid chromatography (HLPC). The normal range for the percent total glycated hemoglobin is 4.8-7.8% and for the percent HbA1c is 4.4-6.4%.

Ion capture occurs by charge attraction. The glass-fiber matrix reaction cell is pre-coated with a soluble affinity reagent coupled to a high molecular weight quaternary ammonium compound. This compound imparts a positive charge to the matrix that allows it to attract (capture) negatively charged analyte complexes such as glycated hemoglobin. The interaction with the cationic matrix separates glycated hemoglobin from non-glycated hemoglobin components. Glycated hemoglobin is then quantified by measuring fluorescence quenching, a naturally occurring property of hemoglobin.

Limitations of the Abbott IMx are minimal. This analyzer is not inhibited by the hemoglobin variants of F, S, and C, labile pre-HbA1c, or uremia (Goldstein et al., 1995). Three internal system processes are used to maintain temperature consistency since this type of analysis is known to be temperature sensitive (Fiore, Mitchell, Doan, Nelson, Winter, & Grandone, 1988). A potential exists for the collection of whole blood insoluble material on the probe, and ultimately the matrix, occluding fluorescence reading. However, this can be avoided with proper cleaning and visual checks. The greatest interference is caused by the host-specific factors of recent acute blood loss and hemolytic anemias.

The IMx is partially able to control for host-specific limitations. The Abbott processor detects elevated hemoglobin levels equal to or greater than 12 mM Hb (19.2 gm/dl) and notifies the technician of the need for manual dilution, which is

described in both the package insert and department operating instruction. In cases of low hemoglobin (devoid of specimen hemolysis), such as with a hemolytic anemia or with a recent major blood loss, correction by processing is not possible; results may inaccurately reflect metabolic control (persons with these medical problems will be excluded from the study).

Performance and precision testing of the Abbott IMx demonstrated between-run coefficients of 4.9%, 4.8%, and 5.1% in three samples (n = 576) where the mean percent glycated hemoglobin measured 5.2%, 9.9%, and 17.2% respectively. Linearity was demonstrated with respect to both hemoglobin concentration (1-12 mM) and glycated hemoglobin concentration (0.1-2.4 mM).

Specificity was determined by studying the interference of triglycerides (up to 3000 mg/dl) and bilirubin (up to 20 mg/dl). Neither of these factors had a significant effect on the IMx Glycated Hemoglobin values. No interference from labile hemoglobins was identified when whole blood samples were incubated with a glucose concentration of 1400 mg/dl at 37 degrees centigrade for three hours. Hemolysis prior to assay also showed no significant effects on IMx Glycated Hemoglobin values.

Accuracy was confirmed by correlational studies with three other commercial diagnostic glycation kits. The percent glycated hemoglobin revealed correlation coefficients of 0.97 or greater in these tests (0.97, n = 648; 0.97, n = 405; 0.98, n = 150).

Multiple quality controls are recommended in the literature and by the manufacturer of the IMx; the laboratory used for this research has adopted or exceeded these recommendations. First, the IMx Glycated Hemoglobin Reagent Pack and Ion Capture Reaction Cells, which arrive as one package, are calibrated and used together per manufacturer instruction. Each time a new lot number of reagents (package) is initiated, duplicate processing of six buffered human

hemoglobin solutions is performed. Once calibration is established, a single point Mode 1 Calibrator is run with *three* control solutions per each patient specimen carousel *every time* the test is run. This procedure far exceeds the minimum established by the manufacturer requiring *one* control per carousel *every eight hours.* Identification of a control that is out of range will stop all processing. The technician will investigate the analyzer, the reagents, and his technique for problems. No results are released until controls are within acceptable ranges.

Other interventions implemented by this laboratory and the manufacturer to control assay or technical limitations include: (1) the use of yellow-colored funnels to differentiate glycated hemoglobin reactions cells from those used for other IMx procedures, (2) the dating of reagents upon arrival and upon opening for expiration (6 Months), (3) the storage of reagents at 2-8 degrees centigrade, (3) the performance of five gentle reagent inversions to maintain uniformity prior to use, (4) the cleaning of the probe with a specific IMx solution after each run to prevent hemoglobin build-up, (5) the visualization of each reaction cell prior to each run assessing for accumulated whole-blood type insoluble materials that might inhibit accurate fluorescence reading through the glass-fiber matrix, and (6) the replacement of reaction cells (to include recalibration) if particulate matter cannot be removed.

Appendix E

Letters of Approval

Wright State University-Miami Valley
College of Nursing and Health

AGENCY PERMISSION FOR CONDUCTING STUDY

THE 74th Medical Group, Wright-Patterson AFB, OH 45433

GRANTS PERMISSION TO Maj. Lisa M. A. Randall, USAF, NC

a student enrolled in a program of nursing leading to a Master's degree at Wright State University, the privilege of using its facilities in order to study the following problem: SELF-EFFICACY, SELF-CARE AND METABOLIC CONTROL IN PERSONS WITH TYPE II, DIET AND EXERCISE CONTROLLED DIABETES.

The conditions mutually agreed upon are as follows:

1. The agency (may) (may not) be identified in the final report.
2. The names of consultative or administrative personnel in the agency (may) (may not) be identified in the final report.
3. The agency (wants) (does not want) a conference with the student when the report is completed.
4. Other: Need final report when study is complete

Date: 7 Oct 97

Thomas M. Korosci

THOMAS M. KOROSCIL, Lt Col, USAF, MC
Chair, Institutional Review Board

Lisa M. A. Randall

Lisa M. A. Randall, Maj, USAF, NC

Kristine Scordo

Kristine A. Scordo, Ph.D., RN

11 Sep 1997

MEMORANDUM FOR CLINICAL INVESTIGATIONS
MAJ LISA M. A. RANDALL

FROM: MAJ COLLINS/NURSING RESEARCH FUNCTION

SUBJECT: Research Proposal

1. The nursing research committee met on 11 September 1997 at 1200. First, I would like to commend you for a job well done. Your research study is approved pending reevaluation of the statistical methods for research question #2. We are sending your proposal forward to meet the Institutional Review Board (IRB) since the statistical methods write-up does not interfere with the data collection portion of your study.

2. At the next meeting, a contact person will be assigned to assist you in any way. Again, congratulations for your tremendous efforts and good luck to you!

Theresa L Collins

THERESA L. COLLINS, Maj, USAF, NC
Chair, Nursing Research Function

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR FORCE MATERIEL COMMAND
WRIGHT-PATTERSON AIR FORCE BASE, OHIO

8 October 1997

MEMORANDUM FOR 74TH MDG/SGN
ATTN: MAJ LISA RANDALL

FROM: 74th Medical Group/SGHT
4881 Sugar Maple Drive
WPAFB OH 45433-5529

SUBJECT: Proposed Clinical Investigation Protocol

1. Your Clinical Investigation protocol "Self-Efficacy, Self-Care and Metabolic Control in Persons With Type II, Diet and Exercise Controlled Diabetes," was reviewed by the full Institutional Review Board of Wright-Patterson Medical Center on 6 October 1997 and assigned tracking number F-WP-H-98-0001. The protocol and informed consent document were approved with the following changes:

a. Prepare informed consent document

b. Remove question J from Personal Information Data Sheet

2. Once revisions are received, the protocol package will be forwarded to the medical center commander for approval. When approval has been received you may begin enrolling subjects. I will let you know once this approval is received. This package will also be forwarded to the Surgeon General's Research Oversight Committee (SGROC) for review.

3. If you have any questions, I can be reached at 74242.

D Bachman
DEBBIE BACHMAN
Clinical Investigations Coordinator

Wright State University

Research and
Sponsored Programs
3640 Colonel Glenn Hwy.
Dayton, OH 45435-0001
(937) 775-2425
FAX (937) 775-3781

e-mail: rsp@wright.edu

DATE: December 9, 1997

TO: Lisa M.A. Randall, P.I., Student
Kristine A. Scordo, Ph.D., Faculty Advisor
College Of Nursing & Health

FROM: Robyn Simmons, Sponsored Programs Assistant
Secretary, WSU Institutional Review Board

SUBJECT: SC# 1923 #2
Self-Efficacy, Self-Care And Metabolic Control In Persons With Type II, Diet And Exercise Controlled Diabetes

This memo is to verify the receipt and acceptance of your response to the conditions placed on the above referenced human subjects protocol/amendment.

These conditions were lifted on: December 9, 1997

This study/amendment now has full approval and you are free to begin the research project. This implies the following:

1. That this approval is for one year from the approval date shown on the Action Form and if it extends beyond this period a request for an extension is required. (Also see expiration date on the Action Form)

2. That a progress report must be submitted before an extension of the approved one-year period can be granted.

3. That any change in the protocol must be approved by the IRB; otherwise approval is terminated.

If you have any questions concerning the condition(s), please contact me at 775-2425.

Thank you!

/rds

Enclosure

2 September 1997

MEMORANDUM FOR The Clinical Investigations Office
74th Medical Group
Wright-Patterson AFB, OH 45433
ATTENTION: Maj Crites

FROM: Maj Lisa M.A. Randall
1875 Edith Marie Dr.
Beavercreek OH 45431
(937) 431-0139

SUBJECT: Permission to access patient information for research.

1. I am writing to you as an AFIT-sponsored, active duty Air Force nurse who is attending Wright-State University to achieve a Masters of Science degree in Adult Health. To fulfill graduate requirements, I plan to conduct a research study on self-efficacy, self-care and metabolic control in persons with Type II, diet and exercise controlled diabetes at the 74th Medical Group.

2. To begin this research, I am requesting permission to access the subject's medical records and computer data base (CHCS) to screen for exclusion criteria and to obtain and/or verify general demographic and diabetes-related information. The information would be used solely for these purposes, and would be kept confidential. Subjects will be notified of this action via the research cover letter, and will be afforded the opportunity to refuse this access during a follow-up phone call made one week after the cover letter is sent.

3. Authorization to access this information would be greatly appreciated. If there are further questions about the research, please contact me at the above number. Thank you for your attention.

Lisa M.A. Randall

LISA M. A. RANDALL, Maj, USAF, NC
181-54-7271

1st Ind: Clinical Investigations Office

TO: Director of Clinical Investigations

APPROVED/DISAPPROVED

5 Sept 97
Date

GERALD E. CRITES, Maj , USAF, MC
Director, Clinical Investigations

2 September 1997

MEMORANDUM FOR The Department of Endocrinology, Diabetes and Metabolism
74th Medical Group
Wright-Patterson AFB, OH 45433
ATTENTION: Dr. Thomas M. Koroscil

FROM: Maj Lisa M.A. Randall
1875 Edith Marie Dr.
Beavercreek OH 45431
(937) 431-0139

SUBJECT: Permission to use your name for laboratory requests.

1. I am writing to you as an AFIT-sponsored, active duty Air Force nurse who is attending Wright-State University to achieve a Masters of Science degree in Adult Health. To fulfill graduate requirements, I plan to conduct a research study on self-efficacy, self-care and metabolic control in persons with Type II, diet and exercise controlled diabetes at the 74th Medical Group.

2. Subjects will be recruited from referrals made to two consecutive Diabetes Patient Education Programs. Pre and post program measures of self-efficacy, self-care and metabolic control will be conducted, with the post measure completed four months from the program's end. Self-efficacy and self-care will be measured by Likert scales, while metabolic control will be measured by glycosylated hemoglobin (HbA1c).

3. To acquire the HbA1c measures, I am seeking permission to *use your name* as the provider for the laboratory order entry requests. As I am sure you are aware, this is the current practice employed by your certified diabetes educators for patients of the Diabetes Patient Education Program. Accountability will be maintained by ensuring you see each subjects pre and post measure results.

4. Authorization to use your name solely for the purposes indicated would be greatly appreciated. If there are further questions about the research, please contact me at the above number. Thank you for your attention.

Lisa M.A. Randall

LISA M. A. RANDALL, Maj, USAF, NC
181-54-7271

1st Ind: The Department of Endocrinology, Diabetes and Metabolism

TO: Chief of Endocrinology, Diabetes and Metabolism

(APPROVED)/DISAPPROVED

9-8-97
Date

Thomas M Koroscil

THOMAS M. KOROSCIL, Lt Col, USAF, MC
Chief, Endocrinology, Diabetes and Metabolism

5 September 1997

MEMORANDUM FOR: Col. Ann C. Hurley
Geriatric Research Education and Clinical Center
Edith Nourse Rogers Memorial Veterans Hospital
200 Springs Road
Bedford, MA 01730

FROM: Lisa M.A. Randall
1875 Edith Marie Dr.
Beavercreek OH 45431
(937) 431-0139

SUBJECT: Request to Modify the Insulin Management Diabetes Self-Efficacy (IMDSES) and the Insulin Management Diabetes Self-Care (IMSCS) Scales

Dear Col Hurley,

1. As a graduate nursing student at Wright State University in Dayton Ohio, I am developing my thesis proposal entitled "Self-Efficacy, Self-Care and Metabolic Control in Persons with Type II, Diet and Exercise Controlled Diabetes". In previous correspondence, I discussed modifications that I wished to make to the IMDSES and the IMDSCS so that these scales could be used in a population of Type II, diet and exercise controlled diabetics. This letter is written to clarify those modifications, and seek your approval for use of the scales as such.

2. Modifications to both scales would include the deletion of the insulin subscale except for the general blood glucose monitoring items (16, 17 & 18). The scales would then be renamed the *Nonmedication-Taking Diabetes Self-Efficacy Scale (NMTDSES)* and the *Nonmedication-Taking Diabetes Self-Care Scale (NMTDSCS)* to avoid confusion. Reliability will be re-evaluated.

3. The NMTDSES and the NMTDSCS will be piloted in the specified population who attend a multi-session, multidisciplinary, outpatient diabetes patient education program. Pre and post measures will be conducted using the scales, and a glycosylated hemoglobin. Post measures will be completed four months from the program completion. Variable relationships and pre and post score differences will be examined.

4. Thank you in advance for you attention and assistance with this study. Please contact me at the above phone number for any concerns.

Lisa M.A. Randall

LISA M. A. RANDALL, Maj, USAF, NC

1st Ind: Geriatric Research Education and Clinical Center

TO: Associate Director for Education and Program Evaluation

APPROVED/DISAPPROVED

9/10/97

Date

Ann C. Hurley

ANN C. HURLEY, Col, USAR, NC

8/11

4 August 1997

MEMORANDUM FOR: Behavioral Medicine
Permission Department
1319 18th Street NW
Washington, DC 20036 - 1802

FROM: Lisa M.A. Randall
1875 Edith Marie Dr.
Beavercreek OH 45431
(937) 431-0139

SUBJECT: Request to Reproduce Material

1. As a graduate nursing student at Wright State University in Dayton Ohio, I am currently developing my thesis proposal entitled "Self-Efficacy, Self-Care and Metabolic Control in Persons with Type II, Diet and Exercise Controlled Diabetes". Recently, I discovered **Dr. C. David Jenkins' article, "An Integrated Behavioral Medicine Approach to Improving Care of Patients with Diabetes Mellitus", in your Summer 1995 edition of Behavioral Medicine (Vol. 21, pp. 53-65).** I truly enjoyed Dr. Jenkins' article, and feel his philosophy of diabetes care provides the most appropriate framework to guide my research.

2. Of particular interest to me, is Dr. Jenkins' conceptual model for evaluating integrated diabetes management programs located on **page 61 (Figure 3).** With your permission, I would like to reproduce this figure for use in my thesis. Dr. Jenkins' conceptual framework will be used as a schematic to highlight and explain the relationships of self-efficacy, self-care and metabolic control in the integrated care setting.

3. Thank you in advance for you time and consideration. Should there be any questions, or if there is a charge for reproduction privileges, please contact me at the above address or phone number. A letter of approval would greatly be appreciated.

9/8/97 Permission granted. Credit:

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Lisa M.A. Randall

LISA M.A. RANDALL, Capt, USAF, NC

Mary Jaine Winokur
Copyright Officer
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1319 18th Street N.W.
Washington, D.C. 20036-1802
Telephone: 202-296-6267 Ext. 225
Fax: 202-296-5149

Appendix F

Informed Consent

Notification of Selection for Research Study

(date)

Dear_____,

My name is Maj. Lisa M. A. Randall. I am an active duty Air Force nurse working towards my Master's degree in Adult Health Nursing. I am a full-time student at Wright State University (WSU) under the sponsorship of the Air Force Institute of Technology (AFIT).

This letter is to invite you to participate in my research study which is required for graduation. The topic of my research is "Self-Efficacy, Self-Care, and Metabolic Control in Persons with Type 2, Diet and Exercise Controlled Diabetes". Because I am a diabetes educator, I am interested in factors that contribute to the self-care skills you perform everyday, and how these factors relate to diabetes control.

I plan to evaluate three concepts. A brief explanation is offered to help you understand the research:

- **Self-Efficacy** is the belief you have regarding your *capability* to monitor, plan, and carry out your diabetes activities of daily living. An example would be:
  - "I feel confident that I can...."
    - stay on my diabetic diet when I eat in unfamiliar places.
    - test my blood sugar as often as the doctor instructed.

- **Self-Care** pertains to the *actual behaviors or actions you perform* daily to maintain control of your diabetes. An example would be:
  - "I (did)...."
    - stayed on my diabetic diet when I ate in unfamiliar places.
    - tested my blood sugar as often as the doctor instructed.

- **Metabolic Control** is the degree of physiological (internal) control you actually attain in your diabetes management. Metabolic control is measured by a lab test that is recommended by the American Diabetes Association for evaluating diabetes. This test is called a glycated hemoglobin, or commonly referred to as a "hemoglobin A1c", or just "A1c". To perform the hemoglobin A1c, one (1) tube or 2 ml (less than 1/2 a teaspoon) of blood would be drawn.

In an attempt to answer other questions you may have, I have provided further information below.

1. **How were you chosen?** You became eligible by simply being referred to the Diabetes Patient Education Program, and having Type 2, diet and exercise controlled diabetes.

2. **What will you need to do?**
   - *Attend a two (2) hour meeting held just prior to the start of the first class.* During this meeting, the study will be reviewed and all pre-program requirements completed to include the signed informed consent, self-efficacy and self-care questionnaires, personal data information sheet

(demographics), and collection of the blood specimen for the HbA1c. A certified diabetes educator (CDE) from the Internal Medicine Clinic will assist with these procedures.

- Note: Because the hemoglobin A1c is a standard of diabetes care and management, your primary provider may have already performed this test. If so, this value will be used *unless* no record of this value is found, the recorded HbA1c is greater than two weeks old by the first day of class, or the HbA1c has been processed at a lab outside this facility. Your results will be reviewed by the endocrinologist or CDE to maintain accountability.

- *Attend all eight (8) sessions of the Diabetes Patient Education Program* as recommended by your provider.

- *Complete all three (3) measures and two (2) additional historical questions four months (120 days) after completing the Diabetes Patient Education Program.* You will be notified of the exact date that these final measures are due at the last class of the Diabetes Patient Education Program. You will have from two (2) weeks before until two (2) weeks after this date to complete the questionnaires, the two historical questions, and the lab test. If these measures have not been completed by two (2) weeks from this 120-day point, you will receive a phone call to ask if you are willing to complete the study.

  - *The self-efficacy and self-care questionnaires, and a six-item (6) post-study questionnaire will be mailed to you 2 weeks prior to this 120-day point.* The six-item post-study questionnaire inquires about events that might have occurred during the study, and asks you to describe how your diet and activity have changed since the Diabetes Patient Education Program. This information will not be shared with your health care provider, and is not an evaluation of how well you are complying with what you have been taught. A self-addressed stamped envelope will be available to return the questionnaires, or you may seal this envelope and return it to a CDE in the clinic.

  - *You will also receive a phone call around the time that the questionnaires are mailed informing you whether a hemoglobin A1c will need to be drawn.* As stated above, this test will only be performed if there is no result already available in your records, the recorded HbA1c is greater than two weeks old by the posted 120-day point, or the HbA1c has been processed at a lab outside this facility. You will have this specimen drawn in the facility's laboratory.

3. **What risks, discomforts or inconveniences are involved?**
   - *The risks associated with obtaining blood for the hemoglobin A1c are no greater than that of other routine blood work.* There is potential for mild discomfort, bruising, clot formation, swelling, inflammation or infection.

   - *The time and effort you expend to complete the study in its entirety.* From start to finish, you will be enrolled in the study five (5) months. The

Diabetes Patient Education Program consists of eight sessions with a total instruction time of 15 hours. The estimated time needed to complete all measures at each interval is 1 hour and 20 minutes. However, because the post measure hemoglobin A1c will be drawn routinely in the facility's laboratory setting, waiting time will depend on the business of the lab.

4. **What benefits will I receive if I choose to participate?** Potentially none, other than knowing you participated in a research study that will add to the knowledge of diabetes management, and possibly contribute to changes that improve the way people with diabetes are taught. A copy of the findings can be sent to you when available, and I will ask you this at the pre-program meeting.

5. **Will the information I provide be kept confidential?** Yes. A coding system will be used where a number will be assigned to the information you provide. Only I will have access to the master list which will be kept in a locked firebox at my home, and I am the only one with a key.

6. **What will happen if I choose not to participate?** Nothing. Your participation is totally voluntary. I will call to verify your participation and answer questions. If you decide not to participate, the care that you are to receive at this hospital will not change in any way.

7. **Do I have the right to withdraw at anytime?** Of course. I would ask though, that you strongly consider your commitment to fulfilling all parts of the study up front.

8. **What if I have further questions?** I will be glad to assist you in anyway possible. I may limit the information I offer, because I would not want to influence or bias your thoughts or actions. You may also contact my faculty advisor, Dr. Kristine A. Scordo, 410 Allyn Hall, Miami Valley College of Nursing and Health, Wright State University, Dayton, OH, 45435 at (937) 775-2628.

Lastly, because I am an active duty US Air Force nurse officer completing my masters degree under the sponsorship of the AFIT, the 74th Medical Group, Wright-Patterson AFB, OH 45433, has authorized this researcher access to her subject's medical records and hospital computer data base (CHCS) to obtain or verify information necessary to complete this study. **Your right to privacy is protected by the opportunity to refuse this researcher access to this information. I will not access this information until I contact you within the next week.** If you choose not to allow this researcher access to this information, then you will not be able to participate in the study.

Thank you so much for time and attention.

LISA M. A. RANDALL, Maj, USAF, NC
Primary Investigator
(937) 431-0139

KRISTINE A. SCORDO, Ph.D., RN
Faculty Advisor
(937) 775-2628

INFORMED CONSENT DOCUMENT

74TH MEDICAL GROUP
Wright-Patterson Medical Center
4881 Sugar Maple Drive
Wright-Patterson AFB OH 45433-5529

Privacy Act of 1974 applies. DD Form 2005 filed in Clinical/Medical Records.

PRIVACY ISSUES: *Records of my participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 USC 552a, and its implementing regulations. DD Form 2005 contains the Privacy Act Statement for the records. I understand that records of this study may be inspected by the U.S. Food and Drug Administration (FDA), the sponsoring agency and/or their designee, if applicable.*

TITLE OF STUDY

SELF-EFFICACY, SELF-CARE, AND METABOLIC CONTROL IN PERSONS WITH TYPE 2, DIET AND EXERCISE CONTROLLED DIABETES

INVESTIGATORS' NAMES, DEPARTMENTS, PHONE NUMBERS

Lisa M. A. Randall, Maj, USAF, NC, AFIT/CI, Wright State University, Dayton, OH (937) 431-0139
Susan C. Agee, RN, Diabetes Care Nurse Educator, SGOMI, 74th Medical Group, Wright-Patterson AFB, OH, (937) 257-1786
Kristine A. Scordo, Ph.D., RN, Faculty Advisor, Wright State University, Dayton, OH, (937) 775-2628

PURPOSE OF STUDY

(This section will explain the nature, purpose(s), approximate number of subjects, and the duration of participants' involvement)

I, _____, SSN _____, willingly agree to participate in this investigation, which has been explained to me by _____. The purpose of this research study is to clarify the relationships among self-efficacy, self-care and metabolic control, and to examine the effects that an outpatient, integrated, multidisciplinary care effort has on these same variables in a population of persons with Type 2, diet and exercise controlled diabetes. Approximately 20 persons with Type 2, diet and exercise controlled diabetes will be enrolled in this study. I will be involved in this study six (6) months.

Subject's Initials_____Date_____

PROCEDURES

(Explains all procedures and the purpose of the procedures to be undergone as part of this study. Any experimental procedures will be explained as such)

I will be expected to participate in all eight (8) sessions of the Diabetes Patient Education Program, and complete two (2) questionnaires (one for self-efficacy; one for self-care) and a laboratory test that evaluates my diabetes (glycated hemoglobin or hemoglobin A1c). The self-efficacy and self-care questionnaires will be administered, and hemoglobin A1c drawn prior to the start of the Diabetes Patient Education Program, and then again at four (4) months from program completion. Additionally, I will need to complete a personal data information sheet (demographic record) with the pre-program measures, and six historical questions with the post-program measures.

BENEFITS

There are no benefits other than knowing I participated in a research study that will add to the knowledge of diabetes management, and possibly contribute to changes that improve the way people with diabetes are taught. I may also receive a copy of the study findings when they are available.

ALTERNATIVES

(This section will explain your alternative treatment possibilities)

The alternative is not to participate in this study. If I choose not to participate, my entitlements to care will not be prejudiced.

RISKS/INCONVENIENCES

(Any discomfort , risks, inconveniences caused from procedures or drugs used that may be expected from participation in this study)

Inconveniences associated with this study include the time and effort I expend to complete two sets of questionnaires twice, a personal data information sheet once, the six historical questions and all eight of the Diabetes Patient Education Program sessions. The risks associated with drawing my blood are considered minimal because they are no greater than the risks associated with other routine lab work (minor discomfort, bruising, swelling, bleeding, inflammation or infection).

Subject's Initials_____Date_____

EVENT OF INJURY

I understand that my entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if I have questions about my rights or if I believe I have received a research-related injury, I may contact the Chief of the Medical Staff at (513) 257-9129, the Director of Clinical Investigations at (513) 257-1542, and/or the investigator, MAJOR LISA M. A. RANDALL at (937) 431-0139.

OCCURRENCE OF UNANTICIPATED EVENT

If an unanticipated event (clinical or medical misadventure) occurs during my participation in this study, I will be informed. If I am not competent at the time to understand the nature of the event, such information will be brought to the attention of my guardian or next of kin.

DECISION TO PARTICIPATE

The decision to participate in this study is completely voluntary on my part. No one has coerced or intimidated me into participating in this program. I am participating because I want to. My investigator(s) has adequately answered any and all questions I have about this study, my participation, and the procedures involved. I understand that the investigator will be available to answer any questions concerning procedures throughout this study. I understand that if significant new findings develop during the course of this study that may relate to my decision to continue participation, I will be informed. I further understand that I may withdraw this consent at any time and discontinue further participation in this study without prejudice to my entitlement to care. I also understand that the investigator of this study may terminate my participation in this study at any time if he/she feels this to be in my best interest. I have been provided a copy of this consent form.

My signature below indicates my willingness to participate in this research study

_____ (Subject's Printed Name)		_____ (Subject's SSN)
_____ (Subject's Signature)	(___) _____ (FMP & Sponsor's SSN)	_____ (Date)
_____ (Advising Investigator's Signature)	_____ (Investigator's SSN)	_____ (Date)
_____ (Witness's Signature)	_____ (Witness's SSN)	_____ (Date)

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